



Catalogue of veterinary products

Before using veterinary medicinal products, please read the package leaflet provided with the product.

For information regarding each medicinal product, please contact the marketing authorisation holder.

Details of the offer are available from company representatives and at the company's headquarters.

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Active ingredients and products list

- · Apiwarol fumigation tablets
- Biowar strips

Ascorbic acid

- Vitaminum C Biowet Puławy injectable solution
 - Immunex complex compound preparation, capsules

Betaglucan

- Bioimmunex canis compound preparation, capsules
- Bioimmunex felis compound preparation, capsules
- Canifos betaglukan compound preparation, tablets
- Canifos junior compound preparation, tablets
- Immunex complex compound preparation, powder

• Olderm – compound preparation, capsules twist-off. Calcium (chloride/gluconate/phosphate)

- Calcigluc compound preparation, injectable solution
- Calcii borogluconas 25% inj. injectable solution
- Calemfos compound preparation, oral solution
- · Calem plus compound preparation, oral solution
- Calmagluc compound preparation, injectable solution

· Elisol - compound preparation, oral solution Caffeine

• Coffenal - injectable solution

Chondroitin (sulfate), glucosamine (hydrochloride)

- Bioarthrex compound preparation, tablets
- Bioarthrex HA compound preparation, tablets

- · Urometin compound preparation, capsules
- Urometin forte compound preparation, capsules

Enrofloxacin

- Enflocyna 50 mg/ml injectable solution
- Enflocyna 100 mg/ml injectable solution
- Enflocyna Sol oral solution

Flumethasone

Vecort – injectable solution

• Gentamycyna Biowet Puławy - injectable solution

- Calmagluc compound preparation, injectable solution
- Immunex complex compound preparation, capsules
- Injectio Glucosi 40% injectable solution
- Rehydrat compound preparation, powder
 Rehydrat C compound preparation, powder

Hyaluronic acid

- Bioarthrex HA compound preparation, tablets
- Hyalsept compound preparation, gel

Iodine, sodium iodide

• Hyalsept - compound preparation, gel

Iron (complexed with dextran)

Suiferrin – injectable solution

Ketamine

• Ketamina Biowet Puławy – injectable solution

L-arginine

NeoplasmaVet amino – compound preparation, capsules

L-glutamine

• NeoplasmaVet amino - compound preparation, capsules

L-methionine

- Urometin compound preparation, capsules
- Urometin forte compound preparation, capsules

Lysozyme dimer

• Lydium-KLP - injectable solution

Magnesium (chloride/gluconate)

- Calcigluc injectable solution
- Calemfos compound preparation, oral solution
- Calem plus compound preparation, oral solution
 Calmagluc injectable solution
- Elisol compound preparation, oral solution

Medroxy progesterone (acetate)

Depogeston – injectable suspension

Oxytetracycline (hydrochloride/dihydrate)

Oxytan 200 – injectable solution

Oxytocin

Oxytocinum Biowet Puławy – injectable solution

Ornithine

- Biohepanex compound preparation, capsules
- Biohepanex forte compound preparation, capsules

Pentobarbital, sodium pentobarbital

- Morbital compound preparation, injectable solution
- Morbital Plus compound preparation, injectable solution

- powder

Phospholipids

- Biohepanex compound preparation, capsules
- Biohepanex forte compound preparation, capsules

Potassium chloride

- Rehydrat compound preparation, powder
- Rehydrat C compound preparation, powder

Propylene glycol

• Boviketozin B₁₂ – compound preparation, oral solution

Quercetin

- NeoplasmaVet compound preparation, capsules
- NeoplasmaVet amino compound preparation, capsules

Sodium chloride

- Elisol compound preparation, oral solution
- Rehydrat prep. compound preparation, tablets
 Rehydrat C compound preparation, powder

Sodium metamizole

• Injectio Pyralgini Biowet Puławy – injectable solution

Sov lecithin

- Biohepanex compound preparation, capsules
- Biohepanex forte compound preparation, capsules

Sulfacetamide (sodium), sulfadymidine (sodium), sulfathiazole (sodium)

· Polisulfamid - compound preparation, injectable solution

Sulfodoxine, trimethoprim

Sultrim – injectable solution

Taurine, trans-resveratrol

• NeoplasmaVet – compound preparation, capsules · NeoplasmaVet amino - compound preparation, capsules

Thiamine (hydrochloride)

Vitaminum B₁ Biowet Puławy – injectable solution

Tiamfenicol

• Tiamfenikol Biowet Puławy – injectable solution

Vaccines

- Aptovac injectable emulsion
- Bovitrichovac injectable suspension
- Mycosalmovir injectable emulsion
- PM-VAC injectable emulsion · Salmovir - injectable emulsion
- Streptovac injectable emulsion

Vitamins C i D,

- Urometin compound preparation, capsules
- Urometin forte compound preparation, capsules

Xylazine

• Sedazin - injectable solution

Zinc

• Olderm - compound preparation, capsules twist-off.

Other preparations (care products, feed mixtures, medical

- devices for diagnostics) Antygen brucella abortus do OKAP – diagnostic
 - Antygen brucella abortus do OWD diagnostic
 - Apistym compound preparation, liquid
 - Avituberculin diagnostic
 - Bovituberculin diagnostic
 - Brucellognost diagnostic
 - Deodent compound preparation, oral solution Mastiprewent – compound preparation, ointment
 - Mlek-test diagnostic
 - Oticlar compound preparation, liquid
 - Testoket diagnostic



Index of products by therapeutic indication

Anesthetics, sedatives, and euthanasia

agents

Ketamina Biowet Puławy

Morbital Morbital Plus

Sedazin®

Antibiotics and sulfonamides

Enflocyna® 50 mg/ml, inj.

Enflocyna® 100 mg/ml, inj.

Enflocyna® Sol

Gentamycin Biowet Puławy

Oxytan 200 Polisulfamid®

Sultrim

Thiamfenikol Biowet Puławy

Calcium and electrolyte products

Calcigluc®

Calcii borogluconas 25% inj.

Calemfos
Calem® plus
Calmagluc®
Elisol

Rehydrat® Rehydrat C

Cardiovascular and stimulant products

Coffenal

Corticosteroids (systemic)

Vecort

Diagnostic medical devices

Brucella Abortus Antigen for OKAP Brucella Abortus Antigen for OWD

Avituberculin Bovituberculin Brucellognost Mlek-test® Testoket

Ectoparasite control products

Biowar Insectin®

Gastrointestinal products

Biohepanex forte Boviketozin B₁₂® **Hormonal products**

Depogeston®

Oxytocinum Biowet Puławy

Immune-stimulating products

Apistym

Bioimmunex canis Bioimmunex felis Canifos betaglukan

Immunex complex powder

Lydium-KLP

Mineral and vitamin products

Canifos®

Canifos® betaglukan Canifos® junior

Vitaminum B1 Biowet Puławy
Vitaminum C Biowet Puławy
Pain and antipyretic products

Injectio Pyralgini Biowet Puławy

Vecort

Products for musculoskeletal disorders

Bioarthrex Bioarthrex HA

Skin and ear care products

Deodent®

Mastiprewent®

Oticlar®

Urinary system products

Urometin
Urometin forte
Vaccines
Aptovac®
Bovitrichovac®
Mycosalmovir®
PM-VAC®

Salmovir® Streptovac

Veterinary anthelmintics

Suiferrin



Index of animal species and products

Bees

- · Apistym compound preparation, liquid
- Apiwarol fumigation tablets
- Biowar strips

Cattle

- Antigen Brucella abortus for OKAP diagnostic
- Antigen Brucella abortus for CFT diagnostic
- · Avituberculin diagnostic
- Boviketozin B₁₂ compound preparation, oral liquid
- Bovitrichovac injection suspension
- Brucellognost diagnostic
- Bovituberculin diagnostic
- Calcigluc compound preparation, injection solution
- · Calcii borogluconas 25% inj. injection solution
- Calem plus compound preparation, oral solution
- Calemfos compound preparation, oral solution
- Calmagluc compound preparation, injection solution
- Coffenal injection solution
- Enflocyna 100 mg/ml injection solution
- Enflocyna 50 mg/ml injection solution
- Enflocyna Sol oral solution
- Hyalsept compound preparation, gel
- Injectio Glucosi 40% injection solution
- Injectio Pyralgini Biowet Puławy injection solution
- Lydium-KLP injection solution
- Mastiprewent compound preparation, ointment
- Mlek-test diagnostic
- Morbital Plus compound preparation, injection solution
- Oxytan 200 injection solution
- Oxytocinum Biowet Puławy injection solution
- Polisulfamid compound preparation, injection solution
- Rehydrat compound preparation, powder
- Rehydrat C compound preparation, powder
- Sedazin injection solution
- Suiferrin injection solution
- Sultrim injection solution
- Testoket diagnostic
- Tiamfenikol Biowet Puławy injection solution
- Vitaminum B₁ Biowet Puławy injection solution
- Vitaminum C Biowet Puławy injection solution

Cats

- Biohepanex compound preparation, capsules
- Bioimmunex felis compound preparation, capsules
- · Coffenal injection solution
- Deodent compound preparation, oral liquid
- Depogeston injection suspension
- Enflocyna 50 mg/ml injection solution
- Gentamycyna Biowet Puławy injection solution

- Hyalsept compound preparation, gel
- Injectio Glucosi 40% injection solution
- Ketamina Biowet Puławy injection solution
- Morbital compound preparation, injection solution
- Morbital Plus compound preparation, injection solution
- NeoplasmaVet amino compound preparation, capsules
- Oticlar compound preparation, liquid
- · Oxytocinum Biowet Puławy injection solution
- Sedazin injection solution
- Urometin compound preparation, capsules
- Vecort injection solution
- Vitaminum C Biowet Puławy injection solution

Dogs

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- Biohepanex forte compound preparation, capsules
- Bioimmunex canis compound preparation, capsules
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- Calmagluc compound preparation, injection solution
- · Canifos compound preparation, tablets
- Canifos betaglucan compound preparation, tablets
- Canifos junior compound preparation, tablets
- Coffenal injection solution
- · Deodent compound preparation, oral liquid
- Depogeston injection suspension
- Enflocyna 50 mg/ml injection solution
- Enflocyna Sol oral solution
- Gentamycin Biowet Puławy injection solution
- Hyalsept compound preparation, gel
- Injectio Glucosi 40% injection solution
- Injectio Pyralgini Biowet Puławy injection solution
- Insectin powder
- Ketamina Biowet Puławy injection solution
- Morbital compound preparation, injection solution
- Morbital Plus compound preparation, injection solution
- NeoplasmaVet compound preparation, capsules
- Oticlar compound preparation, liquid
- Oxytocinum Biowet Puławy injection solution
- Polisulfamid compound preparation, injection solution
- Sedazin injection solution
- Urometin compound preparation, capsules
- Urometin forte compound preparation, capsules
- Vecort injection solution
- Vitaminum B₁ Biowet Puławy injection
- Vitaminum C Biowet Puławy injection solution



Index of animal species and products

Doves

- Elisol compound preparation, oral liquid
- Enflocyna Sol oral solution
- Immunex complex compound preparation, powder
- · Insectin powder
- Mycosalmovir injection emulsion
- PM-VAC injection emulsion
- Salmovir injection emulsion

Foxes

- Vecort injection solution
- Vitaminum C Biowet Puławy injection solution

Goats

- Coffenal injection solution
- Enflocyna 50 mg/ml injection solution
- Injectio Glucosi 40% injection solution
- Mastiprewent compound preparation, ointment
- Rehydrat compound preparation, powder
- Rehydrat C compound preparation, powder

Horses

- Calcigluc compound preparation, injection solution
- Calcii borogluconas 25% inj. injection solution
- Calmagluc compound preparation, injection solution
- Coffenal injection solution
- Hyalsept compound preparation, gel
- Injectio Glucosi 40% injection solution
- Injectio Pyralgini Biowet Puławy injection solution
- Lydium-KLP injection solution
- Morbital Plus compound preparation, injection solution
- Oxytocinum Biowet Puławy injection solution
- Polisulfamid compound preparation, injection solution
- Rehydrat compound preparation, powder
- Rehydrat C compound preparation, powder
- Sedazin injection solution
- Sultrim injection solution
- Vitaminum B₁ Biowet Puławy injection solution
- Vitaminum C Biowet Puławy injection solution

Pias

- Aptovac injection emulsion
- Calcigluc compound preparation, injection solution

- Calcii borogluconas 25% inj. injection solution
- Calmagluc compound preparation, injection solution
- Coffenal injection solution
- Enflocyna 100 mg/ml injection solution
- Enflocyna 50 mg/ml injection solution
- Enflocyna Sol oral solution
- Injectio Glucosi 40% injection solution
- Injectio Pyralgini Biowet Puławy injection solution
- Lydium-KLP injection solution
- Morbital Plus compound preparation, injection solution
- Oxytan 200 injection solution
- Oxytocinum Biowet Puławy injection solution
- Polisulfalent compound preparation, injection solution
- Polisulfamid compound preparation, injection solution
- Rehydrat compound preparation, powder
- Suiferrin injection solution
- Sultrim injection solution
- Streptovac injection emulsion

Poultry (Chickens & Turkeys)

- Enflocyna Sol oral solution
- Vitaminum B₁ Biowet Puławy injection solution

Sheep

- Boviketozin B12 compound preparation, oral liquid
- Coffenal injection solution
- Enflocyna 50 mg/ml injection solution
- Injectio Glucosi 40% injection solution
- Oxytocinum Biowet Puławy injection solution
- Polisulfamid compound preparation, injection solution
- Rehydrat compound preparation, powder
- Rehydrat C compound preparation, powder
- Vitaminum B₁ Biowet Puławy injection solution
- Vitaminum C Biowet Puławy injection solutio



Antygen Brucella Abortus do OKAP



Standardized suspension of inactivated *Brucella abortus* cells for the acidified plate agglutination test

Intended use

Brucella abortus antigen for OKAP is an in vitro diagnostic product used in veterinary medicine. The preparation is intended for laboratory testing for brucellosis using the acid plate agglutination test.

Composition

Suspension of inactivated *Brucella abortus* strain S-99 cells, stained with Bengal rose, suspended in lactate buffer with the addition of 0.5% phenol.

Instructions for use

Shake well before use.

Use according to Instruction No. 27/2003 of the Chief Veterinary Officer dated June 25, 2003 (Ref. No. GIW VII.420/lab-4/2003).

Storage conditions

Store at $+2^{\circ}$ C to $+8^{\circ}$ C.

Protect from light.

Warnings

Do not freeze.

Keep out of sight and reach of children.

User precautions

In case of contact with eyes or skin, rinse thoroughly with plenty of water.

Package contents

20 ml

For veterinary use only.

Marketing authorization number: ZM-067/5319/234B/11 SPC: 2014-04-04



Antygen Brucella Abortus do OWD



Standardized Brucella abortus suspension for the complement fixation test (CFT)

Intended use

Brucella Abortus Antigen for CFT is an in vitro diagnostic product used in veterinary medicine. The preparation is intended for laboratory testing to diagnose animal brucellosis using the Complement Fixation Test (CFT) method.

Composition

Suspension of inactivated Brucella abortus strain S-99 in physiological saline.

Instructions for use

Shake well before use.

Use in accordance with Instruction No. 28/2003 of the Chief Veterinary Officer, dated June 25, 2003 (Ref. No. GIW VII.420/lab-5/2003).

Storage conditions

Store at a temperature of +2°C to +8°C.

Protect from light.

Warnings

Do not freeze.

Keep out of sight and reach of children.

User precautions

In case of contact with eyes or skin, rinse thoroughly with plenty of water.

Package contents

10 ml

For veterinary use only

Listed in the register of in vitro diagnostic products of the Chief Veterinary Officer.

Marketing authorization number: PL/WR 000043





immune support for honeybee colonies





Immunity-Boosting Product for Bees (ginseng extract, lactic acid, sucrose)





- accelerates bee development
- preparation based on natural ingredients, with no withdrawal period for honey

Ingredients in 1000 ml: sucrose 500 g

Additives per 1000 ml:

2b Ginseng Extract 50 g; 2b08004 Lactic Acid 8,3 ml Moisture Content: 45%

Analytical Composition per kg: total protein 226 g, crude fiber 4.12 g, crude ash 516 g, phosphorus 86.6 g

Indications

Apistym is used to improve the condition of bee colonies. Its use enhances the resistance of bee colonies to diseases, particularly nosemosis caused by Nosema apis and Nosema ceranae.

Properties

The ginseng extract contained in Apistym stimulates the production of phenoloxidase, an enzyme involved in immune response, thereby increasing colony resistance and vitality. This helps bees combat pathogen infections more effectively. Autumn administration of Apistym improves the winter survival rate of bee colonies.

Spring application accelerates colony development.

Dosage and administration

Shake well before use!

<u>Preparation of Apistym with Sugar Syrup:</u>

Autumn feeding -4 ml of Apistym per 1 liter of sugar syrup. Drizzling between comb frames & stimulative feeding -20 ml of Apistym per 1 liter of sugar syrup.

Syrup temperature should not exceed 50°C.

Autumn use

Apistym should be mixed with sugar syrup or ready-made bee feed at a concentration of 4 ml per 1 liter of syrup. The prepared mixture should be given to bee colonies during autumn feeding.

The amount of feed should be adjusted to the colony's strength.

Recommended dose per colony: 40 ml Apistym (equivalent to 10 liters of syrup).

If a smaller amount of syrup is used, additional drizzling of comb spaces is recommended, twice at 7–10 day intervals, using 5–10 ml per comb space of a 20 ml Apistym per 1 liter syrup solution.

Spring and summer use

Drizzle comb spaces with 20 ml Apistym per 1 liter of syrup, applying 5-10 ml per comb space twice at 7-10 day intervals. The prepared solution can also be used for stimulatory feeding at a rate of 0.5-1 liter per colony.

Apistym can be mixed with bee feed paste at 4 ml per 1 kg of feed paste per colony.

Storage and handling

Use immediately after opening.

If not fully used, store in a refrigerator for up to 14 days. Keep in a cool, dry place.

Packaging & shelf life Packaging size: 200 ml

Shelf life: 18 months

Apistym was developed in collaboration with research institutions: UMCS Lublin, University of Life Sciences in Lublin, and Jagiellonian University in Kraków. Its formulation is patent-protected, and its effectiveness has been confirmed through laboratory studies and practical use in apiaries.

Veterinary identification number: α Pl0614003p Leaflet preparation date: 2024-10-24







Fumigation tablets for diagnosing and combating bee varroosis. (amitraz 12,5 mg/tablet)

Composition

Amitraz 12.5 mg/tablet

Therapeutic indications

Diagnosing and combating varroosis caused by *Varroa* destructor.

Contraindications

Do not use during production of honey intended for human consumption.

Do not conduct fumigation at the temperature below $+10^{\circ}$ C. Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Adverse reactions

Improper use of the product may lead to brood dying. Fumigation may cause bee agitation.

Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from https://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Amount to be administered per species, method and route of administration

One tablet contains one therapeutic dose sufficient for a single fumigation of a honey bee colony.

Hold a tablet with the tongs and set it on fire, blowing off any possibly emerging flame. Place the smouldering tablet on a narrow (3-4 cm) strip of thick metal netting or specially bent wire feeder, enabling access of air to the tablet. Introduce the smouldering tablet together with the netting into the hive through the entrance, and place it on the bottom board beneath the frames. Cover the entrance for 20 minutes. Next, uncover the entrance and check if the tablet has burnt completely. If not, repeat the procedure. While diagnosing varroosis, adhere to the above procedure, after placing a sheet of paper covered with vegetable fat at the bottom board. Remove the sheet of paper and check for presence of the mites on it an hour after fumigation.

Instructions for use

Apiwarol is exclusively effective on *Varroa destructor* mite attached to the body of the bee. It does not destroy the mites and its developmental forms found on encrusted brood. The best results in varroosis treatment are obtained if fumigation is applied twice in spring and two or three times in autumn at of 4-6 day intervals, when there is the smallest amount of encrusted brood in the hive. In the honey production period, varroosis should be fought by cutting off the encrusted drone brood.

Fumigation should be performed in the evening, after bees have completed their flight. As amitraz is likely to penetrate into honey, autumn treatment should be performed after stock of honey intended for human consumption is removed from the hive.

Withdrawal period

Honey - 5 days

Do not use during production of honey intended for human consumption.

Special precautions for storage

Keep out of the sight and reach of children.

Store below 25°C. Store in a tightly closed container to protect from light and humidity. Do not use this veterinary medicinal product after the use-by date given on the label. Shelf life after first opening the packaging – 24 days.

Special warnings

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Effect of Amitraz on human body has not been fully recognised. Wear a protective mask during the procedure to avoid smoke inhalation. In case of observing any alarming symptoms following exposure to the product, such as vomiting, cardiac arrhythmia or any nervous system disorders, immediately seek doctor's assistance and present the doctor with the information leaflet or package. People with known hypersensitivity to any ingredient of Apiwarol should avoid contact with the veterinary medicinal product. Do not eat, drink or smoke during the procedure. Wash hands after the procedure is complete.

<u>Interaction with other medicinal products and other forms of interaction: Unknown.</u>

 $\underline{Overdose\,(symptoms, emergency\,procedures, antidotes):}$

Administration (burning in the hive) of a larger number of tablets than recommended may cause excessive agitation of bees

Pharmaceutical incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products Amitraz is toxic for fish, therefore attention must be paid to prevent disposal of the product to any bodies of water. Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Package size: An LDPE container with a lid, containing 25 tablets, wrapped in a cardboard box.

Shelf life: 1 year **Other information**

For more information about this veterinary medicinal product, contact the Marketing Authorization Holder.

For animal treatment only.

Subject to medical prescription –
prescription drug.

Tobe administered under veterinary supervision.

SPC: 2015-09-30









Inactivated vaccine for pigs against respiratory infections

${\bf Emulsion \ for \ intramus cular \ injection \ for \ pigs.}$

Active substance and excipient content

One dose (2 ml) contains:

inactivated antigen: Pasteurella multocida not less than 1 ELISA* unit, Inactivated antigen: Actinobacillus pleuropneumoniae serotype 2 not less than 1 ELISA* unit, Inactivated antigen: Actinobacillus pleuropneumoniae serotype 6 not less than 1 ELISA* unit

Adjuvants: Aluminum hydroxide gel 0.1 ml, Emulsigen (mineral oil) 0.2 ml

* 1 ELISA unit – amount of antigen sufficient to obtain antigen to antibody ratio (seroconversion) equal or above 1.8 in vaccinated mice.

Therapeutic indications

Passive immunization of piglets through active immunization of sows and gilts, as well as active immunization of weaners and fatteners, in order to reduce mortality, signs and lesions caused by *Actinobacillus pleuropneumoniae* serotype 2 or 6 and Pasteurella multocida. Onset of immunity is observed 2 weeks after vaccination. Degree of resistance is to a significant extent determined by proper nutrition and zoohygienic conditions.

Contraindications

Do not vaccinate sick animals.

Adverse reactions

A rare adverse reaction is body temperature increased by $2^{\circ}C$ within a few hours after administration of the product. The temperature gets back to normal without any treatment. Inflammatory reaction may occur at the vaccination site, and it resolves spontaneously.

Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from https://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Amount to be administered per species, method and route of administration

2 ml of the product administered to piglets as intramuscular injection near the neck. Vaccination plan for pig farms affected by infections caused by *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* in piglets less than 10 weeks old.

Sows and gilts: first vaccination: 6 – 8 weeks prior to farrowing, second vaccination: 3 – 4 weeks prior to farrowing,

repeated vaccination: 3 – 4 weeks prior to next farrowing. Vaccination plan for facilities with mixed infections caused by

Actinobacillus pleuropneumoniae and Pasteurella multocida reported in weaners and fatteners.

<u>Weaners:</u> after weaning or after piglet purchase, immunize animals twice with 3-week intervals

Instructions for use

Prior to vaccination operations, heat the product to ambient temperature and mix the bottle content thoroughly, immediately before injection. Schedule vaccinations to use entire package content immediately after opening.

Withdrawal period

Zero days.

Special precautions for storage

Keep out of the sight and reach of children. Store in a refrigerator (+2 to +8°C). Do not freeze. Protect from light. Once opened, use the contents of the immediate package immediately. Do not use this veterinary medicinal product after the use-by date given on the label. Expiry date refers to the last day of a given month.

Special warnings

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user: This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician: This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Pregnancy:

There are no contraindications for using this product during pregnancy.

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of the vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Pharmaceutical incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with any other veterinary medicinal products.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required.

These measures should help to protect the environment.

Pack size: 100 ml
Expiry date: 1 year
For animal treatment only
Subject to medical prescription –
prescription drug
Tobe administered under
veterinary supervision.

Marketing authorisation number: 1263/02

SPC 2014-08-01



www.biowet.pl e-mail: export@biowet.pl Aptova

Avituberculin



The product is intended for comparative tuberculin testing of bovine tuberculosis, solution for injection.

Composition

Each ml contains:

Active substance:

Avian tuberculin, purified protein derivative from $Mycobacterium\ avium\ strain\ D_4ER,\ 25\,000\ IU$

Excipient: phenol 5 mg

Clear, colourless or straw-yellow solution

Target species

Cattle

Indications for use

Product intended for use in comparative tuberculin tests for detecting bovine tuberculosis.

Contraindications

None

Special warnings

Special warnings:

Do not use the veterinary medicinal product in animals less than $6\,\text{weeks}$ of age.

Do not repeat the tuberculin test earlier than after 42 days of the last administration of the product.

Do not use the product within 2 weeks before and 2 weeks after parturition.

Do not use the product simultaneously with glucocorticoids.

Special precautions for safe use in the target species:

None

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Avoid contact with skin and mucous membranes. In case of accidental spillage, wash the contaminated areas thoroughly with clean water. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

No adverse effect on pregnancy and lactation was identified. Due to a higher risk of false negative results, tuberculin testing should not be performed in the period within 2 weeks before and 2 weeks after delivery.

Interaction with other medicinal products and other forms of interaction:

Using the product simultaneously with glucocorticoids or other immunosuppressants may reduce the reaction to tuberculin and produce false negative results.

Overdose:

The only effect of multiple administrations of the product is decreased animal susceptibility to subsequent tuberculin doses. This poses no threat to animal health or life.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

None reported.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this

package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Al. Jerozolimskie 181C.

PL-02-222 Warsaw

Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605 https://smz.ezdrowie.gov.pl

Dosage for each target species, route(s) and method(s) of administration

The product is injected intradermally in a dose of $0.1\,\text{ml}$, which corresponds to $2500\,\text{IU}$ of tuberculin.

Advice on correct administration

Tuberculn test procedure

When administering comparative tuberculin test, the injection site for avian tuberculin should be situated approximately 10 cm from the neck crest, and the injection site for bovine tuberculin is approximately 12.5 cm below. In young animals in which there is no room to separate the sites sufficiently on one side of the neck, one injection must be made on each side of the neck at identical sites in the centre of the middle third of the neck

No pathological lesions should be present on the skin within 5 cm from the planned injection site. Before administering the product, the injection site should be marked by clipping the hair in the form of a cross with arms 2-3 cm long. Next, the fold of skin within each clipped area should be taken between the forefinger and thumb, its thickness measured with callipers graduated in millimetres. A dose of tuberculin should be injected intradermally. A needle, bevel edge outwards, should be inserted obliquely into the deeper layers of the skin. A correct injection is confirmed by palpating a small pea-like swelling at the site of the injection.

Tuberculin reactions should be interpreted 72 (± 4) hours after injection of the product. The site of the injection should be inspected and skin-fold thickness re-measured.

Interpretation

Interpretation of reactions to administration of tuberculin in

cattle should be based on clinical observations and differences found in skinfold thickness at the injection site.





Avituberculin



The product is intended for comparative tuberculin testing of bovine tuberculosis, solution for injection.

<u>Comparative tuberculin test</u> – a single intradermal injection of bovine tuberculin simultaneously with a single intradermal injection of avian tuberculin, and interpretation of the reaction:

- a) positive reaction (+): a positive reaction to bovine tuberculin which means that the increase in skin thickness is more than 4 mm greater than the reaction to avian tuberculin, or the presence of clinical signs;
- inconclusive reaction (+/-): a positive or inconclusive reaction to bovine tuberculin which means that the increase in skin thickness is 1 mm to 4 mm greater than the reaction to avian tuberculin, with absence of clinical signs;
- negative reaction (-): a negative reaction to bovine tuberculin, or positive or inconclusive reaction to bovine tuberculin which means that the increase in skin thickness is equal to or less than the reaction to avian tuberculin, and the absence of clinical signs.

The official interpretation of the results of tuberculin tests and handling of animals is regulated by the instructions of the

Withdrawal period(s)

Meat and offal – zero days.

Milk-zero days.

Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2°C-8°C).

Protect from light.

Do not freeze.

Shelf life after first opening the immediate package: 24 hours. Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Detailed information on this veterinary medicinal product is available in the Union Product Database

(https://medicines.health.europa.eu/veterinary).

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Biowet Puławy Sp. z o.o.

Henryka Arciucha 2

24-100 Puławy

Poland

Tel./Fax: + 48 (81) 886 33 53, Tel.: + 48 (81) 888 91 00

e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:

Biowet Puławy Sp. z o.o.

Henryka Arciucha 2

24-100 Puławy

Poland

Tel: +48 (81) 888 91 33, +48 509 750 444

e-mail: biowet@biowet.pl

For animal use only.

Prescription veterinary medicine.

To be administered under the supervision of a veterinarian.

Marketing authorisation number: 2627/17

SPC: 2024-12-09









Bioarthrex

Tablets for dogs supporting cartilage regeneration and the function of the musculoskeletal system





- protects the dog's joints and skeleton
- strengthens and regenerates joint cartilage
- ensures proper joint function and the dog's mobility

Composition (per 2.5 g tablet):

Dicalcium phosphate - 766 mg

Glucosamine (from animal tissues) – $500\,mg$

 $Chondroitin\,sulfate\,-\,400\,mg$

Potato starch - 250 mg

Processed animal protein (poultry) – 150 mg

Wheat starch $-118\,mg$

Brewer's yeast (Saccharomyces cerevisiae) – 70 mg

Magnesium stearate (fatty acid salt) – 50 mg

Porcine gelatin – $20\,mg$

Sensory Additive:

2b/ Harpagophytum procumbens (Devil's Claw Extract) – 60,000 mg/kg

Dietary Additives:

3a300/Ascorbic acid (Vitamin C) - 5,000 mg/kg

3a910/L-carnitine-5,000 mg/kg

3b503/Manganese sulfate monohydrate – 400 mg/kg

Analytical Constituents:

Crude ash - 27.49%

Crude protein - 14.28%

Crude fat – 1.02%

Crude fiber - < 1.0%

Properties

Bioarthrex supports and protects the joints and skeletal system of dogs. Chondroitin and glucosamine aid in cartilage regeneration. Devil's Claw extract (*Harpagophytum procumbens*) helps alleviate symptoms of osteoarthritis. Vitamin C is essential for collagen production. Manganese supports connective tissue regeneration.

Recommended for:

- Active dog breeds with high physical activity
- Dogs at increased risk of musculoskeletal disorders
- Senior dogs for joint support
- Adjunctive support in joint inflammation

Dosage and administration

Initial phase (first 4–6 weeks): 1 tablet per 15 kg of body weight, once daily.

Maintenance dose: 1 tablet per 30 kg of body weight, once

Tablets can be mixed with food for easier administration.

Storage conditions

Store at room temperature in the original packaging. Protect from light and moisture.

Shelf life: 24 months **Tablet weight:** 2.5 g **Quantity:** 90 tablets

Complementary feed for dogs.

Veterinary identification number: 06148301 Leaflet preparation date: 2024-10-28



joint cartilage regeneration



Bioarthrex HA

Tablets for dogs with sodium hyaluronate supporting joint function





- protects the dog's joints and skeleton
- strengthens and regenerates joint cartilage
- ensures proper joint function and the dog's mobility

Composition (per 2.5 g tablet):

Dicalcium phosphate – 600 mg

Glucosamine (from animal tissues) - 500 mg

 $Chondroitin\,sulfate\,-\,400\,mg$

Potato starch – 250 mg

Processed animal protein (poultry) - 150 mg

Wheat starch – 118 mg

Brewer's yeast (Saccharomyces cerevisiae) – 70 mg

Magnesium stearate (fatty acid salt) – 50 mg

Porcine gelatin - 20 mg

Sodium hyaluronate – 15 mg

Sensory Additive:

2b/ Harpagophytum procumbens (Devil's Claw Extract) – 120,000 mg/kg

Dietary additives:

3a300/Ascorbic acid (Vitamin C) – 5,360 mg/kg

3a910/L-carnitine - 5,040 mg/kg

3b503/Manganese sulfate monohydrate - 400 mg/kg

Analytical constituents:

Crude ash - 20.44%

Crude protein - 13.95%

Crude fat – 1.0%

Crude fiber – < 1.0%

Properties

Bioarthrex HA supports cartilage regeneration and improves joint function. Sodium hyaluronate ensures proper joint lubrication. Chondroitin and glucosamine aid in cartilage repair. Devil's Claw extract (*Harpagophytum procumbens*) helps relieve symptoms of osteoarthritis. Vitamin C is essential for collagen production. Manganese supports connective tissue regeneration.

Recommended for:

- active dog breeds with increased physical activity
- dogs at higher risk of musculoskeletal disorders
- senior dogs to support joint health

Dosage and administration

Initial phase (first 4–6 weeks): 1 tablet per 15 kg of body weight, once daily.

Maintenance dose: 1 tablet per 30 kg of body weight, once daily.

Tablets can be mixed with food for easier administration.

Storage conditions

Store at room temperature in the original packaging. Protect from light and moisture.

Shelf life: 24 months Tablet weight: 2.5 g Quantity: 90 tablets

Complementary feed for dogs.



liver protection and regeneration





Capsules for small breed dogs and cats supporting liver function



- phospholipids contained in soy lecithin protect liver cells, support their regeneration, and participate in fat digestion and the absorption of vitamins A, D, E, and K.
- ornithine supports liver function, accelerating the body's detoxification process.

Composition:

wheat starch, fatty acid salt (magnesium stearate) Technological Additives / Emulsifier (per kg): 1c322/Soy lecithin – 110,193 mg (source of phosphatidylcholine)

Technological Additives / Anti-caking Agents (per kg):

1E460/Microcrystalline cellulose – 275,482 mg

1E551b/Colloidal silica – 5,510 mg

Capsule Shell Ingredients:

porcine and bovine gelatin

sensory additive - E172/red

iron oxide – 20,000 mg/kg **Analytical Constituents:**

crude protein - 38.30%

crude fat - 13.30%

crude fiber - 7.40%

crude ash - 2.40%

Properties

The ingredients in Biohepanex support liver regeneration and proper liver function. They aid in liver metabolism, assisting in detoxification. Additionally, they contribute to the digestion of fats and the absorption of fat-soluble vitamins (A, D, E, K).

Recommended for:

- -liver damage, to improve function;
- digestive disorders;
- supportive care for biliary tract diseases;
- cats with hepatic encephalopathy symptom;
- cats weakened due to prolonged food deprivation.

Dosage and administration

1 capsule per 4 kg of body weight, once daily. Capsule contents can be mixed with food. If the pet's diet consists solely of dry food, lightly moisten the food to ensure the powder adheres and is consumed. Consult a veterinarian before use for best results.

Storage conditions

Store in the original packaging at room temperature in a dry

Protect from light and moisture.

Shelf life: 2 years

Packaging: 40 openable capsules (363 mg per capsule)

Complementary feed for small breeds of dogs and cats.







Biohepanex forte

Capsules for medium and large breed dogs supporting liver function





- regenerates the liver and aids digestion
- supports bile duct disorders
- phospholipids protect liver cells and support their regeneration
- ornithine supports liver function and accelerates the body's detoxification process

Composition:

wheat starch, fatty acid salt (magnesium stearate)

 $soy \, lecithin \, (source \, of \, phosphatidylcholine)$

microcrystalline cellulose

Analytical constituents:

crude protein – 46.44%

crude fat – 24.10% crude fiber – 3.30%

crude ash – 3.30%

Properties

The ingredients in Biohepanex Forte support liver regeneration and proper liver function. They aid in liver metabolism, assisting in detoxification. Additionally, they contribute to the digestion of fats and the absorption of fatsoluble vitamins (A, D, E, K).

Recommended for:

- liver damage, to improve function;
- digestive disorders;
- supportive care for biliary tract diseases.

Dosage and administration

1 capsule per 15 kg of body weight, once daily.
Capsule contents can be mixed with food.
If the dog's diet consists solely of dry food, lightly moisten the food to ensure the powder adheres and is consumed.
Consult a veterinarian before use for best results.

Storage conditions

Store in the original packaging at room temperature in a dry place.

Protect from light and moisture.

Shelf life: 2 years

Packaging: 40 openable capsules

${\bf Complementary \, feed \, for \, medium \, and \, large \, breed \, dogs.}$







Bioimmunex canis

Capsules for dogs supporting the body's immunity (product rich in beta-1,3/1,6-D-glucan)





- protects against infections
- neutralizes free radicals

Composition per capsule:

wheat starch, brewer's yeast (Saccharomyces cerevisiae), magnesium stearate (fatty acid salt)

<u>Technological additives / Anti-caking agents per kg:</u>

E460 / Microcrystalline Cellulose 361,011 mg

E551b / Colloidal Silica 7,220 mg

Capsule shell: porcine gelatin

Sensory additives per kg:

E172 / yellow iron oxide 3,026 mg

E132 / indigo carmine 1,316 mg

Analytical constituents:

total protein 79.0%, crude fat 0.5%, crude fiber 12.7%, crude ash 1.0%

Properties:

Bioimmunex Canis contains inactivated yeast, which is a natural source of beta-1,3/1,6-D-Glucan. This compound activates macrophages involved in the body's defense mechanisms. Additionally, β -glucan helps neutralize harmful free radicals.

Indications:

- Supportive therapy for viral, bacterial, fungal, and parasitic diseases.
- For dogs weakened or depleted by long-term antibiotic therapy.
- $As \, an \, adjunct \, treatment \, for \, animals \, diagnosed \, with \, cancer.$
- During recovery, pregnancy, and lactation.
- For periods of reduced immunity and stress (e.g., exhibitions, travel, change of environment).

Dosage & administration:

1 capsule per 20 kg of body weight once daily.

The capsule can be administered directly into the mouth or opened and mixed with food. If feeding exclusively dry food, slightly moisten it to ensure the powder adheres and is fully consumed.

Bioimmunex Canis should ideally be used after consulting a veterinarian.

Storage conditions:

Store in its original packaging at room temperature in a dry place.

Protect from light and moisture.

Shelf life: 2 years

Packaging size: 40 openable capsules (353 mg per capsule)

Complementary feed for dogs.







Bioimmunex felis

Capsules for cats supporting the body's immunity (product rich in beta-1,3/1,6-D-glucan)





- strongly stimulates the body's immune defenses
- supports and enhances immune cell activity
- accelerates tissue regeneration processes

Composition per Capsule

wheat starch, brewer's yeast from saccharomyces cerevisiae, fatty acid salt (magnesium stearate)

Technological additives/Anti-caking agents per kg:

E460 / microcrystalline cellulose – 283,286 mg

E551b/colloidal silica - 5,666 mg

Capsule shell: Porcine-bovine gelatin

Sensory additives per kg:

E172 / Yellow iron oxide – 3,000 mg

E132 / Indigotine – 1,300 mg

Analytical constituents:

crude protein – 79.0%, crude fat – 0.5%, crude fiber – 12.7%, crude ash – 1.0%

Properties

Bioimmunex Felis contains inactivated yeast, a source of beta-1,3/1,6-D-glucan, which activates macrophages involved in the body's defense mechanisms. Additionally, β -glucan supports the neutralization of harmful free radicals.

Indications

- As an adjunct in viral, bacterial, fungal, and parasitic infections;
- For weakened and debilitated cats after prolonged antibiotic therapy;
- As supportive care for animals with cancer;
- During convalescence, pregnancy, and lactation;
- In periods of reduced immunity and stress (e.g., exhibitions, travel, environmental changes).

Administration

Administer 1 capsule daily. The capsule should be given directly into the mouth or opened, with its contents mixed into food. If feeding exclusively dry food, slightly moisten it to ensure the powder adheres to the food and is consumed by the animal.

Bioimmunex Felis is best used after consultation with a veterinarian

Storage conditions

Store in the original packaging at room temperature in a dry

 $Protect\,from\,light\,and\,moisture.$

Shelf life: 2 years

Package size: 40 openable capsules (353 mg/capsule)

Complementary feed for cats.







Strips for hanging in the hive for honey bees (amitraz 500 mg/strip)

Composition

Each strip contains:

Active substance: Amitraz 500 mg

Excipient: Polyethylene

White plastic strip with smooth surfaces.

Indications for use

Control of Varroa mites on bees.

Contraindications

None

Special warnings

Special warnings:

Treat all colonies in the apiary at the same time.

Special precautions to be taken by the person administering

the veterinary medicinal product to animals:

When handling the strips, use protective gloves.

Do not eat, drink, smoke when handling the product.

Avoid contact with skin and eyes when using the strips.

Wash hands with warm water and soap after use.

Avoid contact with food.

Interaction with other medicinal products and other forms of interaction:

Amitraz toxicity increases in the presence of copper salts, and its efficacy deceases in the presence of piperonyl butoxide. Avoid using these substances simultaneously with amitraz.

Overdose:

No adverse effects have been observed after administration of a 5-fold higher doses than the recommended doses for the period of 6 weeks.

Major incompatibilities:

None known

Adverse events
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605,

https://smz.ezdrowie.gov.pl

Dosage for each target species, route(s) and method(s) of administration

The product is to be suspended inside a beehive in a dose: 2 strips/1 hive.

Advice on correct administration

Place strips in aisles between frames where bee activity is the highest. Hang the strips so as to provide free bee access from both sides, which can be done by maintaining proper distance between the frames.

Leave the strips in a hive for 6 weeks, then remove. If bee activity inside the hive is away from the strips, change strip location to place them inside the bee colony, and before removing, leave the strips for another 2 weeks. The strips must be removed after the maximum of 8 weeks. Do not re-use the strips.

It is recommended to administer treatment in all hives at the same time.

Recommended period of treatment: after the last honey harvest (end of summer/autumn) and in spring before the first pollen harvest.

Observe the recommended treatment periods and doses.

Withdrawal period(s)

Honey – zero days.

Do not use during production of honey intended for human consumption.

Special storage precautions

Keep out of the sight and reach of children.

Store below 25°C.

Store in the original, tightly closed container.

Shelf life after first opening the immediate packaging: use immediately.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Special precautions for disposal of the veterinary medicinal product

Medicines should not be disposed of via wastewater or household waste.

This veterinary medicinal product should not enter water courses as amitraz is toxic for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Pack size: 10 strips **Shelf life:** 18 months

Batch expiration date: The contents of an opened package should be used immediately.

Type and composition of immediate packaging: Cardboard box containing 10 strips sealed in a PET/Aluminium/PE sachet.

For animal use only.

Prescription-only veterinary medicine.

To be administered under veterinary supervision.

Marketing authorisation number: 2085/11 SPC: 2025-01-29





rapid response to ketosis

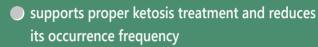


Boviketozin B₁₂

Product for preventing and supporting the proper treatment of ketosis

(propylene glycol, iodine, cobalt, vitamin B₂)





- improves feed intake in animals
- regulates disrupted lactation

Supportive in ketosis and hypoglycemia

Composition per liter

Propylene glycol – 993 ml Dietary additives / Trace elements per kg

3b305 / Cobalt – 0.9 mg 3b201 / lodine – 5.0 mg

Dietary additive / Vitamin per kg

3a835 / Vitamin B₁₂ (Cyanocobalamin) – 9 mg

Analytical constituents

calcium – 44 mg, sodium – <1.0 mg, phosphorus – <1.0 mg, magnesium – <1.0 mg, crude protein – <0.5%, crude ash – <0.5%, crude fat – <1.0%, crude fiber – <0.3%, moisture – >99%

Properties

Propylene glycol increases blood glucose levels and inhibits the formation of ketone bodies. When administered during the periparturient period, it reduces the risk of ketosis and enhances milk yield. Iodine regulates metabolism, increases feed intake, and positively affects reproduction. Cobalt stimulates the development of rumen microflora and is involved in the synthesis of vitamin B_{12} , which plays a key role in red blood cell formation.

Indications

- Reducing the risk of ketosis and hypoglycemia;
- $-\,Supportive\,in\,the\,proper\,treatment\,of\,ketosis;$
- During periods of increased energy demand;
- To enhance feed intake and improve milk yield.

Administration

To be administered during the periparturient period:

Cows – 250 ml once daily from 3 weeks before calving to 6 weeks after calving.

Sheep -60-100 ml once daily from 6 weeks before lambing to 3 weeks after lambing.

The product should be mixed with water or feed, or administered directly into the mouth.

It is recommended to consult a veterinarian before use.

Storage conditions

Store at a temperature up to 25°C in the original, tightly sealed container. Protect from light and moisture.

Shelf life: 2 years **Package size:** 1000 ml

Dietary feed mixture for dairy cows and sheep.



Bovitrichovac



Inactivated vaccine against bovine dermatophytosis, suspension for injection

Composition

1 ml of the vaccine contains: Inactivated strain *Trichophyton verrucosum* 43, minimum concentration 20%

Therapeutic indications

Active immunisation of cattle to reduce mortality rate and clinical symptoms of dermatomycosis induced by *Trichophyton verrucosum* infection.

Therapeutic use in animals with dermatological symptoms of trichophytosis to accelerate recovery. Immunity occurs 3-4 weeks after the second injection. Immunisation period after two administrations is 9-12 months.

Posology and routes of administration

The vaccine should be administered twice at the interval of 10-14 days.

Administer intramuscularly to the muscle of the pelvic limb according the following scheme:

Prophylaxis:

from the age of 1 week to 4 months – 5 ml from the age of 4 to 8 months – 5 ml to 6 ml over 8 months – 6 ml to 7 ml

Treatment:

from the age of 1 week to 4 months – 7.5 ml from the age of 4 to 8 months – 7.5 ml to 9 ml over 8 months – 9 ml to 10.5 ml

The product can be used in animals during pregnancy or lactation.

Recommendations for proper administration

None.

Contraindications

None.

Withdrawal period

Zero days.

Adverse reactions

A slight swelling may occur at the injection site, which remits spontaneously within a few days.

Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from https://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Special precautions for storage and transport

Keep out of the reach and sight of children. Store in a refrigerator (2-8°C). Do not freeze.

Once opened, use within 14 days.

Do not use after the expiry date which is stated on the label.

Special warnings and precautions

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

There is no available information concerning safety and efficiency of the vaccine used in combination with other medicinal veterinary products. Therefore, the decision to use this vaccine before or after administration of another medicinal veterinary product should be considered individually.

After administration of a double dose, no other adverse reactions occurred than those specified in the section concerning adverse reactions.

Since no conformity studies of this veterinary medicinal product have been conducted, this product must not be combined with other medicinal veterinary products.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Shelf life: 12 months **Available containers:** 250 ml

For animal treatment only.

To be administered under veterinary supervision. Subject to medical prescription – prescription drug.

Other information

For further information about this veterinary medicinal product, please contact the marketing authorization holder.

Marketing autorisation number: 480/98 SPC: 2014-04-03





Bovituberculin



Product for the diagnosis of tuberculosis in cattle, solution for injection

Composition

Each ml contains:

Active substance: Bovine tuberculin, purified protein derivative from $Mycobacterium\ bovis\ strain\ AN_s\ 32\ 500\ IU$

Excipient: phenol 5mg

Clear, colourless or straw-yellow solution

Indications for use

Product intended for use in detecting bovine tuberculosis in cattle older than 6 weeks of age infected with *Mycobacterium bovis*

Contraindications

None

Special warnings

Do not use the veterinary medicinal product in animals less than 6 weeks of age.

Do not repeat the tuberculin test earlier than after 42 days of the last administration of the product.

Do not use the product within 2 weeks before and 2 weeks after parturition.

Do not use the product simultaneously with glucocorticoids. Special precautions for safe use in the target species:

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Avoid contact with skin and mucous membranes. In case of accidental spillage, flush the contaminated areas thoroughly with clean water. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

No adverse effect on pregnancy and lactation was identified. Due to a higher risk of false negative results, tuberculin testing should not be performed in the period within 2 weeks before and 2 weeks after parturition.

Interaction with other medicinal products and other forms of interaction:

Using the product simultaneously with glucocorticoids or other immunosuppressants may reduce the reaction to tuberculin and produce false negative results.

Overdose:

The only effect of multiple administrations of the product is decreased animal susceptibility to subsequent tuberculin doses. This poses no threat to animal health or life.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

None reported.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing

authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C, PL-02-222 Warsaw Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605 https://smz.ezdrowie.gov.pl

Dosage for each target species, route(s) and method(s) of administration

The product is injected intradermally in a dose of 0.1 ml, which corresponds to 3250 IU of tuberculin.

Advice on correct administration

Tuberculin test procedure

When administering a single tuberculin test, the injection site should be situated at the border of the anterior and middle thirds of one side of the neck, about 10 cm below the crest.

When administering the comparative (double) tuberculin test, avian and bovine tuberculin should be used simultaneously. The tuberculin injection should be made on both sides of the neck or alternatively, on one selected side of the animal's neck. In case of performing the tuberculin test on one side of the neck, the injection site for the avian tuberculin should be situated at the border of the anterior and middle thirds of one side of the neck, about 10 cm below the crest, whereas the injection site for the bovine tuberculin should be situated about 12.5 to 15.0 cm below, on a line roughly parallel with the line of the shoulder. In young animals in which there is no room to separate the sites sufficiently on one side of the neck, each injection must be made separately on each side of the neck at identical sites in the centre of the middle half of the

No pathological lesions should be present on the skin within 5 cm from the planned injection site. Before administering the product, the injection site should be marked by clipping the hair in the form of a cross with arms 2-3 cm long. Next, the fold of skin within each clipped area should be taken between the forefinger and thumb, its thickness measured with callipers graduated in millimetres. A dose of tuberculin should be injected intradermally. A needle, bevel edge outwards, should be inserted obliquely into the deeper layers of the skin. A correct injection is confirmed by palpating a small pea-like swelling at the site of the injection.





Bovituberculin



Product for the diagnosis of tuberculosis in cattle, solution for injection

Tuberculin reactions should be interpreted 72 (\pm 4) hours after injection of the product. The site of the injection should be inspected and skin-fold thickness re-measured.

Interpretation

Interpretation of reactions to administration of tuberculin in cattle should be based on clinical observations and differences found in skin-fold thickness at the injection site. Single tuberculin test – single intradermal injection of bovine

tuberculin and interpretation of the reaction:

- a), positive reaction (+); if clinical lesions, such as diffuse or extensive oedema, exudation, necrosis, pain or inflammation of lymphatic ducts or lymph nodes in that area are observed or if the increase in skin fold thickness at the injection site is 4.0 mm or greater;
- b). inconclusive reaction (+/-): if no clinical signs listed in item a) are observed, and if the increase in skin fold thickness is greater than 2.0 mm but less than 4.0 mm;
- c). negative reaction (-): if only limited callous oedema is observed with the increase in skin fold thickness not greater than 2.0 mm, without clinical signs.

Comparative tuberculin test – a single intradermal injection of bovine tuberculin simultaneously with a single intradermal injection of avian tuberculin, and interpretation of the reaction:

- a). positive reaction (+): a positive reaction to bovine tuberculin which means that the increase in skin thickness is more than 4 mm greater than the reaction to avian tuberculin, or the presence of clinical signs;
- b). inconclusive reaction (+/-): a positive or inconclusive reaction to bovine tuberculin which means that the increase in skin thickness is 1 mm to 4 mm greater than the reaction to avian tuberculin, with absence of clinical
- c). negative reaction (-): a negative reaction to bovine tuberculin, or positive or inconclusive reaction to bovine tuberculin which means that the increase in skin thickness is equal to or less than the reaction to avian tuberculin, and the absence of clinical signs.

The official interpretation of the results of tuberculin tests and handling of animals is regulated by the instructions of the Chief Veterinary Officer.

Withdrawal periods

Meat and offal – zero days.

Milk-zero hours.

Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C). Protect from light. Do not freeze

Shelf life after first opening the immediate package: 24 hours. Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Detailed information on this veterinary medicinal product is available in the Union Product Database

(https://medicines.health.europa.eu/veterinary).

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Biowet Puławy Sp. z o.o.

Henryka Arciucha 2

24-100 Puławy

Poland

Tel./Fax: +48 (81) 886 33 53, Tel.: +48 (81) 888 91 00

e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:

Biowet Puławy Sp. z o.o.

Henryka Arciucha 2

24-100 Puławy

Poland

Tel: +48 (81) 888 91 33, +48 509 750 444

e-mail: biowet@biowet.pl

Available packaging:

Cardboard box containing 5 vials of 25 doses each.

Shelf life: 2 years

For animal use only.

Prescription-only veterinary medicine. To be administered under veterinary supervision.

Marketing authorisation number: 2628/17 SPC: 2024-12-09







Brucellognost



Standardized suspension of inactivated Brucella abortus cells for tube agglutination

Composition

Suspension of inactivated *Brucella abortus* strain S-99 cells in phosphate buffer with 0.5% phenol.

Intended use

Brucellognost is an in vitro diagnostic product used in veterinary medicine. The preparation is intended for laboratory testing for brucellosis using the antigen agglutination reaction method.

Directions for Use

Shake well before use.

Use in accordance with Instruction No. 26/2003 issued by the Chief Veterinary Officer on June 25, 2003 (No. GIWz. VII. 420/lab-3/2003).

Storage conditions

Store at a temperature of $+2^{\circ}$ C to $+8^{\circ}$ C.

Protect from light.

Warnings

Do not freeze.

Keep out of sight and reach of children.

User precautions

In case of contact with eyes or skin, rinse thoroughly with plenty of water.

Package contents: 100 ml Shelf life: 24 months

For veterinary use.

Product listed in the GLW register of in vitro diagnostic devices.

Marketing authorization number: PL/WR 00041

SPC: 2011-04-06





Calcii borogluconas 25% inj.

Injection solution intendedfor horses, cattle, pigs and dogs (calcium gluconate 216.6 mg/ml)

Composition

1 ml contains:

Active substance:

Calcium gluconate 216.6 mg

Excipient:

Chlorocresol 0.9 mg **Therapeutic indications**

Treatment of calcium metabolism disorders resulting in hypocalcaemia (parturient paresis in cattle, pregnancy toxaemia in dogs, postpartum hypocalcaemia in swine) and conditions with increased neuromuscular excitability (transit tetany) or with paresis of the motor organs for various reasons (Downer cow syndrome).

As a supportive drug in the treatment of hypomagnesemic tetany, inflammatory and allergic conditions, particularly acute ones and with redness, as well as in cases of swelling and reduced blood oagulation.

Contraindications

Do not use in the case of kidney failure, liver failure, hyperparathyroidism and hypocalcaemia.

Adverse reactions

Intravenous administration of high doses of drugs particularly to animals in a general poor condition can result in hypercalcaemia. As a result bradycardia can occur, the strength of the cardiac contractions and frequency of contractions with AV nodal reentrant tachycardia and additional contractions increase. There is an acute myocardial hypoxia, and then muscle shaking, anxiety, sweating, decrease of blood pressure resulting in a collapse.

In order to identify the symptoms of over-dosage at a proper time, the heart beat should be monitored during the infusion. In intramuscular and subcutaneous injections, and also in peri-intravenous administration some local reactions in a form of transient swelling can occur.

Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from https://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Posology per each species, routes and methods of administration

The product should be administered intravenously or intramuscularly. In dogs it can also be administered subcutaneously.

The size of a dose calculated for 1 kg of the body weight should be varied depending on the nature of a disease and a general health condition of an animal:

- $A cute\ hypocal caemia 0.8\ ml\ /\ kg\ of\ body\ weight$
- Acute inflammatory and allergic conditions 0.4 ml / kg of body weight

Poisoning, bleeding diathesis – 0.2 ml/kg of body weight

The above doses should be used once a day. In the case of acute hypocalcaemia a repeated dose can be applied after 6 hours. Subsequent administration of the drug can take place after 24 hours of the last application.

The product should be used for 1-3 days and if necessary the treatment should be extended with the preparation for oral application.

Recommendations for proper administration

In intravenous administration the preparation needs to be heated to the body temperature and injected slowly in the amount of 25-50 ml/min.

In intramuscular and subcutaneous administration the preparation should be applied in several places: 20-40 ml in one place in big animals and 2-3 ml in one place in small ones.

Withdrawal period

Horse, cattle, pigs:

Edible tissues – zero days,

Milk-zero days,

Dog - not applicable.

Special precautions for storage

Keep out of the sight and reach of children.

Store at a temperature below 25°C. Protect from sunlight. Do not freeze

Do not use this veterinary medicinal product after the expiry date given on the label.

Durability after the first opening of the direct package – 28 days.

Special warnings

Special precautions for use in animals:

In order to avoid administration of too high a dose, the bodyweight of an animal has to be determined with the highest possible accuracy. Before intravenous administration the preparation needs to be heated to the body temperature. Do not exceed the recommended speed of infusion. During and directly after the end of administration the heart beat should be monitored. In the case of any cardiac disorders intravenous administration should be immediately stopped.

 $\underline{\text{Special precautions for persons administering the medicinal}} \\ \underline{\text{veterinary product to animals:}}$

Upon random self-injection seek medical help and provide a physician with the leaflet or the packaging.

Pregnancy:

No contraindications to apply during pregnancy.

Lactation:

No contraindications to apply during lactation

Interactions with other medicinal products and other forms of interaction

Do not administer jointly with drugs from the group of cardiac glycosides with preparations including carbonate, phosphate, sulphate ions and with antibiotics from the group of





Calcii borogluconas 25% inj.

Injection solution intended for horses, cattle, pigs and dogs (calcium gluconate 216.6 mg/ml)

tetracyclines. High doses of calcium are administered along with cardiac glycosides (derivatives of strophanthine and digoxin) strengthen their effect and can result in heart rhythm disorders. Thiazide diuretics increase reabsorption of calcium and increase a risk of hypercalcaemia. High doses of calcium administered along with Vitamin D can weaken the effect of drugs blocking the calcium channel.

<u>Overdose</u> (symptoms, procedures concerning immediate help and antidotes):

Overdose results in hypercalcaemia and hypercalcinuria. Symptoms of hypercalcaemia may include: nausea, vomiting, thirst, increased thirst, dehydration and constipation. Longlasting overdose resulting in hypercalcaemia can cause vascular and organ calcification. Calcium supplementation in excess of 2000 mg/day, taken for several months, constitutes a threshold and may be a cause of poisonings.

In the case of over-dosage one must immediately stop the treatment and supplement the fluid deficiency. In the case of long-term over-dosage oral and intravenous rehydration with NaCl solutions should be applied. At the same time (or also after rehydration) loop diuretics (e.g. furosemide) are applied in order to increase calcium excretion and prevent the increase in the fluid volume.

Thiazide diuretics should not be administered.

Pharmaceutical incompatibilities:

Since no studies of the conformity of this veterinary medicinal product have been conducted, this product must not be combined with other medicinal veterinary products.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment

Shelf life: 2 years

Available containers: 250 ml.

Subject to medical prescription – prescription drug. Tobe administered under veterinary supervision. For animal treatment only.

Marketing autorisation number: 1170/01 SPC: 2015-11-17









Injection solution intended for horses, cattle and pigs (magnesium gluconate, calcium gluconate, magnesium chloride hexahydrate, calcium chloride hexahydrate)

Composition

Each ml contains:

Active substances:

Magnesium gluconate60 mgCalcium gluconate60 mgMagnesium chloride hexahydrate30 mgCalcium chloride hexahydrate27 mg

Excipient:

Phenol 2.6 mg

Clear, colourless or slightly yellow solution.

Target species

Horses, cattle, pigs.

Indications for use

Horses: laminitis, urticaria.

<u>Cattle:</u> parturient paresis in cows, disorders of calcium and magnesium metabolism, such as Downer cow syndrome, hypocalcaemia and subclinical hypomagnesemia, acute tetany caused by hypomagnesaemia.

Pigs: postparturient hypocalcaemia in sows, rickets.

Contraindications

Do not use in hyperparathyroidism and end-stage renal failure

Do not use in hypermagnesemia with heart conduction disorders.

Do not use in case of earlier treatment with cardiac glycosides.

Special warnings

Special warnings:

Intravenous injection of high product doses, especially in animals in poor health condition, may lead to hypercalcemia. Special precautions for safe use in the target species:

To avoid administration of an excessively high dose, determine body weight as accurately as possible. In order to recognise symptoms of overdose in good time, monitor heart functions during the injection.

Inject the product slowly at 25-50 ml/minute, warm the product to body temperature before administration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Do not eat, drink and smoke when handling the product.

Take special caution to avoid self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

Cardiac glycosides enhance cardiotoxic action of calcium ions. Beta-adrenergic agonists and methylxanthines enhance the effect of calcium ions on the heart. Simultaneous oral administration of tetracyclines increases binding of calcium ions with proteins. Calcium salts administered orally reduce

intake of tetracyclines and fluoride compounds (a 3-hour interval is required between administration of these drugs and calcium compounds). Vitamin D, parathormone and acidic pH of feed increase calcium intake, whereas calcitonin, glucocorticoids, excessive amount of lipids, alkaline feed, phytate (e.g. in cereal products), oxalates (e.g. in spinach, rhubarb) and phosphates (milk and milk products) reduce calcium intake.

High calcium doses administered simultaneously with cardiac glycosides (strophanthin and digoxin derivatives) enhance their action and may lead to arrhythmia.

Thiazide diuretics boost calcium re-absorption and pose the risk of hypercalcemia.

High calcium doses administered simultaneously with vitamin D may attenuate the effect of verapamil and other calcium channel blockers.

Overdose:

Overdosing the product leads to hypercalcemia and hypermagnesemia, and to increased urinary excretion of calcium and magnesium. Symptoms of hypercalcemia and/or hypermagnesemia may include: nausea, vomiting, polydipsia, polyuria, dehydration and constipation. Long-term overdose leading to hypercalcemia and/or hypermagnesemia may cause vascular and internal organ calcification. Calcium supply of more than 2000 mg/24 hours, over a period of several months constitutes a threshold and may be the cause of poisonings. Arrhythmia is a symptom of overdose. When it occurs, discontinue administration of the product.

In case of overdose, discontinue treatment immediately and replenish fluid deficiency. In case of long-term overdose, use oral and intravenous rehydration with NaCl solutions. Simultaneously (or after rehydration) administer loop diuretics (e.g. Furosemide) in order to increase calcium excretion and prevent the increase in the fluid volume.

Do not administer thiazide diuretics.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

Target species: horses, cattle, pigs.

Very rare (< 1 animal/10 000 animals treated, including isolated reports)

Hypercalcemia¹

¹May occur during intravenous injections, especially in animals in poor health condition.









Injection solution intended for horses, cattle and pigs (magnesium gluconate, calcium gluconate, magnesium chloride hexahydrate, calcium chloride hexahydrate)

In case of hypercalcemia, bradycardia is observed, the power of muscle contraction and contraction rate increase, followed by tachycardia and extra contractions. This results in acute myocardial hypoxia, followed by muscle tremor, anxiety, sweats, lowered blood pressure leading to collapse.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605,

https://smz.ezdrowie.gov.pl.

Dosage for each target species, routes and method of administration

Route of administration: intravenous. Horses, cattle: 0.5 – 1.0 ml/kg b.w. Pigs: 2.0 – 5.0 ml/kg b.w.

Advice on correct administration

Inject the veterinary medicinal product slowly at 25-50 ml/min.

Withdrawal period(s)

Horses, cattle, pigs: Meat and offal – zero days. Cattle:

Milk – zero hours.

Special storage precautions

Keep out of the sight and reach of children.

Store below 25°C. Protect from light. Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Detailed information on this veterinary medicinal product is available in the Union Product Database

(https://medicines.health.europa.eu/veterinary).

Contact details

<u>Marketing authorisation holder and manufacturer</u> responsible for batch release:

Biowet Puławy Sp. z o.o. Henryka Arciucha 2 24-100 Puławy

Poland

Tel./Fax: +48 (81) 886 33 53, Tel.: +48 (81) 888 91 00

e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:

Biowet Puławy Sp. z o.o. Henryka Arciucha 2 24-100 Puławy Poland

Tel: +48 (81) 888 91 33, +48 509 750 444

e-mail: biowet@biowet.pl

Shelf life: 2 years **Package size:** 250 ml

For animal use only.

Prescription-only veterinary medicine.
To be administered exclusively by a veterinarian.

Marketing authorization number: 790/99

SPC: 2024-09-26





compensates for weakness





Oral supplement for dairy cows, replenishing calcium and phosphorus deficiencies during the periparturient period



- provides a source of calcium, magnesium, and phosphorus
- balances energy deficiencies due to glycol content
 - protects the liver thanks to vitamin PP content
 - easy to administer
- available at a competitive price

Composition

calcium carbonate, propylene glycol, dicalcium phosphate, magnesium chloride Dietary Additives per kg

3a315 Niacinamide - 103 mg

<u>Technological</u> additives per kg

 $E\,466\,Carboxymethylcellulose-4,538\,mg$

Analytical constituents (per 595 g)

calcium - 80,325 mg, phosphorus - 9,699 mg, chlorides - 7,438 mg, magnesium - 2,969 mg, sodium - 262 mg, crude ash - 34%, crude protein - <0.5%, crude fiber - <0.3%, crude fat - <1.0%, moisture - 61%

Properties and indications

Calemfos should be administered during periods of increased calcium and phosphorus demand in dairy cows, especially around calving. When used prophylactically, it shortens the postpartum period and reduces the risk of postpartum paresis. Phosphorus enhances calcium absorption and helps maintain the body's acid-base balance. Magnesium improves calcium utilization, supports neuromuscular function, and benefits heart activity. Propylene glycol provides a source of energy. Vitamin PP (Niacinamide) protects the liver from fatty degeneration.

Administration

<u>Administer orally:</u> 595 g (1 bottle) 12 hours before calving, then again 6 to 12 hours after calving, and once more 24 hours after calving.

Shake well before use.

Take precautions to prevent aspiration.

Storage Conditions

Store at room temperature in the original packaging. Protect from light and moisture.

Shelf Life: 18 months **Package Size:** 595 g

Complementary feed mixture for dairy cows.



indispensable during the periparturient period





Oral supplement for cows replenishing calcium and magnesium deficiencies



- replenishes calcium and magnesium deficiencies
- rapid absorption with long-lasting presence in the blood
- does not irritate the fore-stomach mucosa due to the presence of vegetable oil

Composition

heart activity.

calcium chloride, vegetable oil (refined rapeseed oil), magnesium salt of an organic acid (magnesium citrate), alucose

Technological additives per liter

Polysorbate $80 (E433) - 5.62 \, ml$

Analytical constituents per kg

calcium - 91.2 g, magnesium - 2.7 g, sodium - 0.01 g, crude protein - <0.5%, crude fiber - <0.3%, crude ash - 29.3%, crude fat - 25.8%, moisture - 40%

Properties and indications

This product is recommended for dairy cows during periods of increased demand for calcium, magnesium, and glucose. When administered prophylactically during the periparturient period, it prevents a drop in blood calcium levels (hypocalcemia), thereby reducing the risk of postpartum paresis. The magnesium content enhances calcium utilization, supports neuromuscular function, and contributes to proper

Glucose provides an easily absorbed source of energy, reducing the risk of negative energy balance and metabolic disorders.

Administration

Administer orally, 445 ml (1 bottle) approximately 12 hours before calving, then 6 to 12 hours after calving, and again 24 hours after calving.

Shake well before use.

Take precautions to avoid aspiration.

Storage conditions

Store at room temperature in the original packaging. Protect from light and moisture.

Shelf Life: 18 months **Package Size:** 445 ml

Complementary feed mixture for dairy cows.







Injection solution intended for horses, cattle, pigs and dogs (calcium gluconate, calcium hypophosphite, magnesium chloride hexahydrate, glucose monohydrate)

Composition

Each ml contains:

Active substance:

Calcium gluconate 60 mg
Calcium hypophosphite 22 mg
Magnesium chloride hexahydrate 30 mg
Glucose monohydrate 100 mg

Excipient:

Phenol 2.6 mg

Clear, colourless or slightly yellow solution.

Indications for use

Solution for injection is intended for use in horses, cattle, pigs and dogs in case of calcium and magnesium deficiency. The product is used to treat clinical and subclinical hypocalcaemia, hypomagnesemia and hypoglycaemia, parturient paresis in cows, puerperal tetany in dogs, postparturient hypocalcaemia in sows.

This veterinary medicinal product can also be used in treating allergies (particularly urticaria), as well as subacute and chronic disorders of calcium and magnesium metabolism, such as Downer cow syndrome and subclinical hypomagnesemia.

The product is also used in treatment of diseases caused by calcium-phosphate metabolism disorders, such as rickets, osteomalacia and fibrous osteodystrophy. In addition, it is administered during treatment of diseases involving increased neuromuscular excitability, such as e.g. hypomagnesaemia-induced tetany in cattle, tetanus, rhabdomyolysis in horses, as well as inflammations and poisoning with signs of increased vascular permeability, e.g. pulmonary and cerebral oedema, oedema disease in piglets, laminitis in horses (as an ancillary drug).

Contraindications

Hyperparathyroidism and renal failure.

Hypercalcaemia, acidosis.

Hypermagnesemia, Myastenia gravis in dogs, heart conduction disorders.

Earlier treatment with cardiac glycosides, beta-adrenergic agonists and caffeine.

Special warnings

Special warnings:

Take caution when using in animals with poor health condition, in which excessively high product doses may lead to myocardial hypoxia and lowered blood pressure leading to collapse.

Special precautions for safe use in the target species:

In case of intravenous injection, warm the product to body temperature and inject slowly (25 – 50 ml/min in large animals, 15-30 ml/min in small animals). For example: 500 ml of the product in large animals should be administered for not less than 5 to 10 minutes.

To prevent overdosing, determine body weight as accurately as possible.

In order to recognise symptoms of overdose in good time, monitor heart functions during the injection.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Do not eat, drink and smoke when handling the product.

Take special caution to avoid self-injection.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

Cardiac glycosides enhance cardiotoxic action of calcium ions. Beta-adrenergic agonists and methylxanthines enhance the effect of calcium ions on the heart. Simultaneous oral administration of tetracyclines increases binding of calcium ions with proteins.

It is not recommended to use the product simultaneously with thiazide diuretics, glucocorticoids, ion-exchange resins, oxalic and phytic acids, laxatives, e.g. paraffin oil.

Due to magnesium ion content, this veterinary medicinal product can act as an antagonist of other calcium preparations. Magnesium decreases absorption of theophylline, tetracyclines, iron preparations, fluoride compounds, as well as oral anticoagulants, warfarin derivatives from the digestive tract.

Diuretics, cisplatin, cycloserine, mineralocorticoids increase urinary excretion of magnesium. Aminoglycosides, relaxants and colistin used simultaneously with magnesium preparations may cause paralysis. As a result of urine alkalinization, renal clearance of quinidine is reduced, which involves the risk of overdose.

Overdose:

Overdosing the product leads to hypercalcemia and hypermagnesemia, and to increased urinary excretion of calcium and magnesium. Symptoms of hypercalcemia and/or hypermagnesemia may include: nausea, vomiting, polydipsia, polyuria, dehydration and constipation. Long-term overdose leading to hypercalcemia and/or hypermagnesemia may cause vascular and internal organ calcification. In case of overdose, discontinue treatment immediately and replenish fluid deficiency. In case of long-term overdose, use oral and intravenous

rehydration with NaCl solutions. Simultaneously (or after rehydration) administer loop diuretics (e.g. Furosemide) in order to increase calcium excretion and prevent the increase in the fluid volume. Do not administer thiazide diuretics. Arrhythmia is a symptom of overdose. When it occurs, discontinue administration of the product.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal









Injection solution intended for horses, cattle, pigs and dogs (calcium gluconate, calcium hypophosphite, magnesium chloride hexahydrate, glucose monohydrate)

product must not be mixed with other veterinary medicinal products.

Adverse events

Target species: horses, cattle, pigs, dogs.

Very rare (< 1 animal/10 000 animals treated, including isolated reports)

Hypercalcemia¹

¹ May occur during intravenous injection of high product doses, particularly in animals in poor health condition. In case of hypercalcemia, bradycardia is observed, the power of muscle contraction and contraction rate increase, followed by tachycardia and extra contractions. Presented symptoms include sweats, anxiety, muscle tremor, lowered blood pressure leading to collapse; acute myocardial hypoxia is developed.

The safety margin for calcium gluconate, magnesium chloride, calcium hypophosphite and glucose is high, whereas the potential toxic effect requires administration of doses exceeding therapeutic doses multiple times.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605,

https://smz.ezdrowie.gov.pl

Dosage for each target species, routes and method of administration

The product is intended for intravenous or intramuscular use. In horses and dogs, it should be administered intravenously only.

In case of intravenous injection, warm the product to body temperature and inject slowly (25 – 50 ml/min in large animals, 15-30 ml/min in small animals). For example: 500 ml of the product in large animals should be administered for not less than 5 to 10 minutes.

Depending on the disease, administer the product to cattle, horses, pigs and dogs as follows:

Chronic and subacute, both primary and secondary metabolism disorders of basic macronutrients, and diseases caused by calcium-phosphate metabolism disorders, such as rickets, osteomalacia and fibrous osteodystrophy – administer a dose of **0.5 ml/kg bodyweight intravenously or intramuscularly, once daily for 3 to 7 days**. Extend treatment with administration of mineral mixtures.

Acute disorders with advanced hypocalcaemia and hypom-

agnesaemia, such as parturient paresis and tetany caused by hypomagnesaemia – administer a dose of 1.0-1.5 ml/kg bodyweightintravenously or intramuscularly, once, twice and, exceptionally, three times, at 12 hour intervals.

Diseases not directly related to calcium-magnesium metabolism disorders and as a supplement in inflammations, allergies and toxicity (urticaria, laminitis, oedema, increased neuromuscular excitation) – administer a dose of **0.3-0.5 ml/kg**

bodyweight, every second day for 6 to 14 days.

Advice on correct administration

In case of intravenous injection, warm the product to body temperature and inject slowly (25 – 50 ml/min in large animals, 15-30 ml/min in small animals). For example: 500 ml of the product in large animals should be administered for not less than 5 to 10 minutes.

Withdrawal period(s)

Dogs - not applicable.

Cattle, horses, pigs - zero days.

Special storage precautions

Keep out of the sight and reach of children.

Store below 25°C. Protect from light. Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 28 days

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

For animal use only.

Prescription only veterinary medicine.

To be administered exclusively by a veterinarian.

Shelf life: 2 years.

Package size: 250 ml.

Marketing authorization number: 1317/02

SPC 2024-09-26











Tablets for dogs supporting growth and development







- supports healthy growth and development
- ensures proper bone structure and strength
- flavored tablets attract dogs with their appealing scent

Composition per 2.5 g:

dicalcium phosphate – 2102 mg processed animal protein (poultry) – 148 mg starch – 148 mg

brewer's yeast (Saccharomyces cerevisiae) - 70 mg

pork gelatin - 40 mg

fatty acid salt (magnesium stearate) - 24 mg Analytical constituents / tace elements per 2.5 g:

calcium - 620 mg phosphorus - 408 mg

magnesium – 19 mg

potassium – 1.4 mg

sodium - 0.9 mg

zinc - 0.275 mg

iron - 0.036 mg

manganese - 0.023 mg

Analytical Constituents:

crude ash - 78.5%, crude protein - 7.2%, crude fat - 1.4%, crude fiber - 0.3%

Properties and indications

Canifos supplements the diet with essential micro- and macroelements that support healthy growth and development. The product contains a combination of active ingredients essential for the proper formation of bones and teeth, as well as the maintenance of muscle function.

Brewer's yeast enhances the immune system, supports skin and coat health, and aids in digestive processes.

Canifos is recommended to balance the diet with essential nutrients.

Dosage and administration

1 tablet per 10 kg of body weight, twice daily.

Dogs weighing less than 10 kg should be given 1 tablet twice

The tablet can be mixed with food.

Storage conditions

Store at room temperature in the original packaging. Protect from light and moisture.

Shelf life: 24 months Tablet weight: 2.5 g Package size: 90 tablets

Complementary mineral feed for dogs.



fetch for health



Canifos ® betaglukan

Tablets for dogs supporting the immune system (beta-1.3/1.6-D-Glukan)



- saccharomyces cerevisiae yeast is rich in natural polysaccharide beta-1,3/1,6-D-glucan, which activates cells involved in the defense mechanism
- strengthens the body's natural immunity
- contains micro- and macroelements that support development and overall condition

Composition per 2.5 g:

Dicalcium phosphate 1880 mg, processed animal protein (poultry) 350 mg, starch 118 mg, brewer's yeast (Saccharomyces cerevisiae) 70 mg, porcine gelatin 38 mg, fatty acid salt (magnesium stearate) 24 mg

Analytical Constituents:

Crude ash -67.87%, crude protein -9.79%, crude fat -1.39%, crude fiber <1.0%

Trace Elements per 2.5 g:

Calcium 520 mg, phosphorus 358 mg, magnesium 2.4 mg, sodium 3.8 mg, potassium 3.6 mg, iron 2.2 mg, zinc 0.24 mg, manganese 0.025 mg

Properties and indications

Canifos Betaglucan contains active ingredients essential for strengthening the immune system. Brewer's yeast derived from *Saccharomyces cerevisiae* is rich in the natural polysaccharide beta-1,3/1,6-D-glucan, which activates cells involved in immune defense mechanisms, thus enhancing natural immunity. Brewer's yeast also serves as a natural probiotic. The product contains micro- and macroelements that positively affect overall development and physical condition.

Canifos betaglucan is recommended during recovery for animals weakened by illness, during antibiotic therapy, pregnancy and lactation, in stressful situations (such as exhibitions and travel), and for elderly animals.

Dosage

1 tablet per 10 kg of body weight twice daily. The tablet can be mixed with other food.

Storage conditions

Store at room temperature in the original packaging. Protect from light and moisture.

Shelf life: 24 months **Tablet weight:** 2.5 g **Number of tablets:** 90 pcs

Complementary mineral feed for dogs.



healthy, strong bones



Canifos sunior

Dietary supplement tablets for young dogs and pregnant or lactating bitches, providing essential minerals





- prevents mineral deficiencies that can lead to limb rickets
- provides a well-balanced supply of calcium, phosphorus and essential macro- and microelements for proper bone growth
- ontains β-1,3/1,6-D-Glucan, which stimulates the body's immune system

Composition per 2.5 g:

Calcium lactate 1255 mg, dicalcium phosphate 612 mg, processed animal protein (poultry) 350 mg, starch 118 mg, brewer's yeast (*Saccharomyces cerevisiae*) 70 mg, porcine gelatin 40 mg, fatty acid salt (magnesium stearate) 24 mg, magnesium oxide 13 mg.

Analytical constituents:

Crude ash -43.26%, crude protein -10.31%, crude fat -1.23%, crude fiber <1.0%

Trace Elements per 2.5 g:

Calcium 375 mg, phosphorus 126 mg, magnesium 7.8 mg, sodium 3.5 mg, potassium 3.4 mg, iron 1.7 mg, zinc 0.10 mg, manganese 0.025 mg.

Properties and indications

Canifos Junior supplements the diet with macro- and microelements that support healthy growth and development. The calcium and phosphorus in the product ensure proper bone and dental formation. Brewer's yeast derived from *Saccharomyces cerevisiae* is rich in the natural polysaccharide beta-1,3/1,6-D-glucan, which enhances immune function and promotes healthy skin and coat. Additionally, brewer's yeast acts as a natural probiotic, supporting digestive processes.

Canifos Junior is recommended for prophylactic use in pregnant and lactating bitches, as well as in young dogs during periods of intensive growth. Regular administration of the supplement improves overall condition and helps prevent mineral deficiencies.

Dosage:

1 tablet per 5 kg of body weight once daily. The tablet can be mixed with other food for easier administration

Storage Conditions

Store at room temperature in the original packaging. Protect from light and moisture.

Shelf life: 24 months Tablet weight: 2.5 g Number of tablets: 90 pcs

Complementary mineral feed for dogs.







Injection solution intended for horses, cattle, pigs, sheep, goats, dogs and cats (caffeine 80 mg/ml)

Active substance and excipient content

Each 1 ml dose contains:

Active substance:

Caffeine 80 mg

Excipient:

Sodium benzoate (E211) 120 mg

Therapeutic indications

Arrhythmia and cardiovascular failure during infectious, non life-threatening diseases.

Contraindications

Do not use in case of acute heart failure, myocardial ischemia.

Adverse reactions

In case of subcutaneous administration of caffeine, topical reactions due to irritation caused by the product may appear. Intravenous administration may produce anxiety, motor agitation and increased heart rate and arrhythmia. Tachypnea is also observed.

In piglets susceptible to stress for genetic reasons, intravenous injection of caffeine produces typical clinical signs of the impact of stressors, which is manifested in anxiety, motor agitation, emitting noises, increased heart rate and tachypnea, as well as raised creatine phosphokinase activity (after 45 minutes from administration of caffeine). Possible reactions also include gastrointestinal disorders due to increased secretion by gastric glands.

In animals diagnosed with epilepsy, intravenous administration of caffeine may produce convulsions.

Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from https://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Amount to be administered per species, method and route of administration

Product for subcutaneous, intramuscular or intravenous use in the following doses:

- horses, cattle: 5 20 ml
- pigs, sheep, goats: 1.5 7.5 ml
- dogs: 0.25 0.75 ml
- cats: 0.05 0.5 ml

While determining the amount to be administered, consider the current clinical condition of an animal, its weight, route of administration and animal-specific susceptibility to caffeine.

In case of subcutaneous or intramuscular administration, the effect is observed after 15-30 minutes, whereas in case of intravenous administration, it is observed immediately. Under justified circumstances, administer another dose after 6-8 hours.

Indications for use

None

Withdrawal period

Edible tissues:

Horses, cattle, pigs, sheep, goats: zero days

Milk:

Cattle, sheep, goats: zero days

Dogs, cats: not applicable

Special precautions for storage

Keep out of the sight and reach of children.

Store below 25°C. Protect from light. Do not freeze.

Do not use this veterinary medicinal product after the use-by date given on the label.

Shelf life after first opening the immediate packaging: 28 days.

Special warnings

Special precautions for use in animals:

In animals diagnosed with epilepsy, use the product accordingly to the benefit/risk assessment. In case of adverse reactions from the central nervous system, stop administering the drug immediately and start anticonvulsant therapy.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Avoid direct exposure to the product. In case of accidental self-injection, immediately seek doctor's assistance and present the doctor with the information leaflet or package.

Caffeine may be dangerous to human life, if consumed in a dose 5–10 g. Severe poisoning has been reported after taking 1.0 g of caffeine (15 mg/kg of b.w.).

<u>Pregnancy:</u>

The safety of the veterinary medicinal product has not been established during pregnancy.

Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Lactation:

The safety of the veterinary medicinal product has not been established during lactation.

Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Caffeine enhances the effect of digitalis-based products and beta-adrenomimetics.

If used with methylxanthines and beta adrenomimietics (adrenaline, isoprenaline, orciprenaline), potentiation of both drug groups on heart is observed, which is manifested in arrhythmia. Positive inotropic effect of caffeine and cardiac glycosides was observed as well.









Injection solution intendedfor horses, cattle, pigs, sheep, goats, dogs and cats (caffeine 80 mg/ml)

Overdose (symptoms, emergency procedures, antidotes): Caffeine overdose may lead to tachycardia or tachycardia with arrhytmia, blood pressure drop, anxiety. Administration of toxic doses may produce seizures. Moreover, product overdose may lead to stiffness and tremor, increased production of urine. Carnivorous species may respond by vomiting. In case of caffeine overdose, use pentobarbital sodium.

Pharmaceutical incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Package size: 50 ml Shelf life: 2 years

For animal use only. Prescription-only. To be administered under veterinary supervision.

Marketing authorization number: 23/94 SPC: 2016-03-31





to breathe freely





Liquid to prevent bad breath in dogs and cats



- neutralizes unpleasant mouth odor
- prevents tooth decay
- strengthens tooth enamel
- dissolves mineral dental plaque

Composition

- Citric acid
- -Sodium fluoride
- Cetylpyridinium chloride
- Saccharin
- Fragrance
- Distilled water

Characteristics

Gives your pet clean and healthy teeth, neutralizing bad breath.

Fluoride prevents dental caries and strengthens tooth enamel.

Citric acid dissolves mineral plaque.

Fragrance and saccharin enhance flavour and aromatic characteristics of the product.

Indications

Eliminating unpleasant odour from the mouth.

Teeth cleaning and care.

Directions for use

Spray teeth and gums with the product brought to room temperature.

It is enough to press the dispenser 1 to 3 times for each side of the mouth.

In case of animal hypersensitivity to spraying, moisten a cotton pad with the product by pressing the dispenser 3-5 times and apply to teeth by rubbing.

Use the product after each meal.

Use the product daily to keep the teeth clean and healthy.

Storage

Keep at a temperature not exceeding +25°C.

Protect from light.

Do not freeze.

Warnings

 $Keep\ out\ of\ the\ reach\ and\ sight\ of\ children.$

Shelf life: 18 months

Available container

Spray bottles containing 50 ml of the product.

Leaflet preparation date: 2013-10-25



Depogeston



Injection suspension intended for dogs and cats (medroksyprogesteronu octan 50 mg/ml)

Composition

Active substance:

Medroxyprogesterone acetate – 50 mg/mlExcipients: Methyl parahydroxybenzoate – 1.2 mg/ml Propyl parahydroxybenzoate – 0.2 mg/ml

Therapeutic indications

Preventing heat in bitches and queens.

Treating hypersexuality in queens, not associated with polycystic ovaries.

Contraindications

Do not use:

- in proestrus, oestrus, metoestrus phases,
- in pregnant and lactating animals,
- in case of diagnosed mammary gland tumours,
- in immature and growing animals,
- before occurrence of the first heat cycle,
- in diabetic animals,
- in reproductive tract inflammations,
- in English Whippet bitches,
- in cases of hypersensitivity to the active substance or any of the excipients.

Adverse reactions

Administration of medroxyprogesterone for more than 2 years is conducive to uterus and mammary gland disorders. It may cause endometritis pyometra complex in bitches, growth of endometrial tissue, cystic endometrial hyperplasia, polycystic ovaries, acromegaly and mammary gland tumours. Administration of MPA may cause adrenal suppression and diabetes.

Transitory changes in animal temperament and increased appetite may occur during treatment.

In rare cases, skin and fur discolouration or hyperpigmentation may occur at the injection site. Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from

https://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Amount to be administered per species, method and route of administration

Depogeston should be administered subcutaneously or intramuscularly in the following doses:

<u>bitches:</u> 50 – 100 mg of medroxyprogesterone acetate per animal, subcutaneously or intramuscularly, i.e.

- small animals (up to 10 kg of b.w.) 1.0 ml of the product per animal;
- medium (10-25 kg of b.w.) 1.5 ml of the product per animal;
- large (25-45 kg of b.w.) 2.0 ml of the product per animal; queens: 50 mg of medroxyprogesterone acetate per animal,

subcutaneously, i.e. 1.0 ml of the product per animal. First administration of the product should occur not earlier than after 2 months after parturition and not later than 1 month before expected heat.

In order to permanently block the heat cycle, apply this product regularly every 5 months in bitches and every 3-4 months in queens, however not longer than for the period of 2 years. Inform the animal owner that occurrence of the first heat is animal-specific and it usually occurs after about 5-6 months in bitches and 3-4 months in queens, although in some cases this period may be considerably extended.

Instructions for use

Shake the product before use to obtain homogeneous suspension

Withdrawal period

Not applicable

Special precautions for storage

Keep out of the sight and reach of children.

Store below 25°C. Do not freeze.

Do not use this product after the use-by date given on the label

Shelf life after first opening the immediate packaging: 14 days

Special warnings

Special warnings per target species:

Relevant laboratory tests to determine the phase of the cycle should be run before use.

Special precautions for use in animals:

First administration of the product should occur not earlier than after 2 months after parturition and not later than 1 month before expected heat.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Pregnant women and women of childbearing potential should avoid exposure to the product. In case of accidental spilling on skin or contact with eyes, rinse the affected site with water. In case of accidental self-injection, immediately seek doctor's assistance and present the doctor with the information leaflet or package.

Pregnancy:

Do not use during pregnancy.

Lactation:

Do not use while breastfeeding. If administered during breastfeeding, the product suppresses milk secretion by inhibiting secretion of pituitary gonadotropins.

Interaction with other medicinal products and other forms of interaction:

Administration of gonadotropins (LH, FSH) and estrogens for purposes of recovering the heat cycle after product use may increase the risk of pathological lesions of the endometrium.

Overdose (symptoms, emergency procedures, antidotes):

Overdose may cause transitory changes in animal temperament, increased appetite, lactation





Depogeston



Injection suspension intended for dogs and cats (medroksyprogesteronu octan 50 mg/ml)

Pharmaceutical incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Other information

For more information about this veterinary medicinal product, contact the Marketing Authorization Holder.

Pack size

One glass bottle containing 5 ml of the product, wrapped in a cardboard box.

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

For animal treatment only.

Subject to medical prescription – prescription drug Tobe administered under veterinary supervision.

SPC: 2015-09-30





electrolyte support for victorious flights

for victorious flights

Elisol

Multi-electrolyte solution for pigeons and ornamental birds (chlorides: sodium, calcium, and magnesium)





- strengthens the body
- prevents electrolyte loss and dehydration
- replenishes essential nutrients: potassium, iron, sodium, zinc, manganese, copper, calcium and magnesium

Composition

sodium chloride calcium chloride magnesium chloride

Dietary Additives / Trace Elements (per kg)

3b201 potassium iodide - 46 mg

3b102 iron (III) chloride hexahydrate – 1160 mg

3b602 anhydrous zinc chloride – 177 mg

3b501 manganese chloride tetrahydrate – 144 mg

 $3b403\,copper\,chloride\,dihydrate\,-\,54\,mg$

Technological Additives (per kg)

1aE332 potassium citrate – 18,250 mg

1aE331 sodium citrate – 1,910 mg

Analytical Constituents (per 100 ml)

potassium – 643 mg, sodium – 226 mg, calcium – 13.8 mg, magnesium – 10 mg

crude protein -<5%, crude ash -<2%, crude fat -<1%, crude fiber -<1%, moisture -98%

Properties and indications

Elisol rapidly regulates the water-electrolyte balance, strengthens the body, and prevents electrolyte loss and dehydration. The product is recommended during periods of intense physical exertion, especially in the racing season, during illnesses, particularly those associated with diarrhea, in convalescence, during hot weather and in stressful situations (transport, exhibitions, flock rearrangements). It is also beneficial during the intensive feeding period of young birds.

Directions for use

Elisol should be administered in drinking water at a rate of 10 ml per 1 liter of water (daily dose for 20 pigeons or ornamental birds weighing up to 1 kg):

- Preventively: 2 times per week
- During chick-feeding periods, illness, or hot weather: daily
- During the racing season: administer for 2 days before the flight at 10 ml per 1 liter of water and 15 ml per 1 liter of water on the day of return

Use clean water (preferably boiled) for preparation.

Administer in clean containers.

The solution can also be mixed with food.

Storage conditions

Store at room temperature in the original packaging. Protect from light and moisture.

After opening, seal tightly and use within 4 weeks.

Shelf life: 24 months

Package sizes: 100 ml, 500 ml

Complementary feed mixture for pigeons and ornamental birds.

Veterinary identification number: $\alpha PL0614003p$ Leaflet preparation date: 2024-11-13







Injection solution intended for dogs, cats, cattle, sheep, goats and pigs (enrofloxacin 50 mg/ml)

Composition

Each ml contains:

Active substance:

Enrofloxacin – 50 mg

Excipient:

Benzyl alcohol E1519 – 15.7 mg Clear, slightly yellow solution.

Target species

Cattle (calves), sheep, goats, pigs, cats, dogs

Indications for use

Cattle (calves)

Treatment of respiratory infections caused by *Pasteurella multocida, Mannheimia haemolytica and Mycoplasma spp.* susceptible to enrofloxacin.

Treatment of gastrointestinal infections caused by *Escherichia coli* susceptible to enrofloxacin.

Treatment of septicaemia caused by *Escherichia coli* susceptible to enrofloxacin.

Treatment of acute *mycoplasma arthritis* caused by *Mycoplasma bovis* susceptible to enrofloxacin.

Sheep

Treatment of gastrointestinal infections caused by *Escherichia coli* susceptible to enrofloxacin.

Treatment of septicaemia caused by *Escherichia coli* susceptible to enrofloxacin.

Treatment of mastitis caused by *Staphylococcus aureus* and *Escherichia coli* susceptible to enrofloxacin.

Goats

Treatment of respiratory infections caused by *Pasteurella multocida*, *Mannheimia haemolytica* susceptible to enrofloxacin.

Treatment of gastrointestinal infections caused by *Escherichia coli* susceptible to enrofloxacin.

Treatment of septicaemia caused by *Escherichia coli* susceptible to enrofloxacin.

Treatment of mastitis caused by *Staphylococcus aureus* and *Escherichia coli* susceptible to enrofloxacin

Pias

Treatment of respiratory infections caused by Pasteurella multocida, Mycoplasma spp., Actinobacillus pleuropneumoniae susceptible to enrofloxacin.

Treatment of gastrointestinal infections caused by *Escherichia coli* susceptible to enrofloxacin.

Treatment of septicaemia caused by *Escherichia coli* susceptible to enrofloxacin.

Doas

Treatment of gastrointestinal, respiratory and genitourinary infections (including prostatitis, and as antibiotic therapy supporting treatment of metritis), skin and wound infections, otitis (media/externa) caused by Staphylococcus spp., Escherichiacoli, Pasteurella spp., Klebsiella spp., Bordetella spp., Pseudomonas spp. and Proteus spp. susceptible to enrofloxacin.

Cats

Treatment of gastrointestinal, respiratory and genitourinary infections (including prostatitis, and as antibiotic therapy supporting treatment of metritis), skin and wound infections caused by Staphylococcus spp., Escherichiacoli, Pasteurella spp., Klebsiella spp., Bordetella spp., Pseudomonas spp. and Proteus spp., susceptible to enrofloxacin.

Contraindications

Do not use in case of hypersensitivity to enrofloxacin, other fluoroquinolones or to any excipient.

Do not use in animals with epilepsy or seizure episodes, as enrofloxacin can stimulate the central nervous system.

Do not use in growing dogs, that is: less than 8 months of age in small breed dogs, less than 12 months of age in large breed dogs, less than 18 months of age in giant dog breeds, due to the risk of negative impact on joint cartilage development.

Do not use in cats less than 8 weeks of age due to the risk of negative impact on joint cartilage development and retinal degeneration.

Do not use in young horses due to the risk of negative impact on joint cartilage development.

Special warnings

Special precautions for safe use in the target species:

Fluoroquinolones should be used in treating only those diseases in which observed response to administration of other classes of antimicrobial drugs is not satisfactory or the response to treatment is expected to be insufficient.

The product may only be used in treating infections caused by microbes the sensitivity of which was confirmed by results of antimicrobial resistance testing, and in case of resistance to other chemotherapeutics.

Do not use the product to treat less acute infections.

During product use, comply with the applicable national and local guidelines for using antimicrobial drugs.

Using the product contrary to provisions of the Summary of Product Characteristics may lead to increased frequency of microbial resistance to fluoroquinolones and decreased efficacy of treatment using other quinolones due to emergence of a potential cross-resistance.

Caution is advised when using enrofloxacin in animals with renal failure.

Caution is advised when using enrofloxacin in cats, as doses exceeding the recommended doses may cause retinal degeneration and blindness. In

cats below 5 kg body weight, use a dose of 25 mg/ml to avoid overdose.

Degenerative changes in joint cartilage were observed in calves treated with 30 mg of enrofloxacin per kg of body weight, administered per os for 14 days.











Injection solution intended for dogs, cats, cattle, sheep, goats and pigs (enrofloxacin 50 mg/ml)

Use of enrofloxacin in lambs in the recommended dose for 15 days produced histological changes in joint cartilage, not linked to clinical signs.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to fluoroquinolones should avoid contact with the veterinary medicinal product.

Pregnant women should avoid contacting the veterinary medicinal product directly.

Avoid contact with skin and eyes. In case of accidental contact with skin or eyes, immediately flush the affected area with clean water

Wash hands after use.

Do not smoke, eat or drink during preparation and administration of the product.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effect, however they have revealed foetotoxic effect in case of administration of doses inducing maternal toxicity.

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Do not use enrofloxacin simultaneously with antimicrobials acting as quinolone antagonists (e.g. macrolides, tetracyclines or phenicols).

Do not use the product simultaneously with theophylline, as this may lead to increased theophylline concentrations and delay its elimination.

Caution is advised when administering enrofloxacin simultaneously with flunixin in dogs, in order to avoid adverse effects. Reduction in drug clearance as a result of simultaneous administration of flunixin and enrofloxacin indicates that these substances interact during the phase of drug elimination.

That is why simultaneous administration of enrofloxacin and flunixin in dogs leads to increase in AUC and half-life of the drug at the stage of flunixin elimination, and to increase in half-life at the stage of elimination and reduced Cmax of enrofloxacin.

Overdose:

In case of accidental overdose, gastrointestinal (vomiting, diarrhoea) and nervous system disorders may occur.

No adverse effects have been observed in pigs administered five times the recommended dose.

Cats receiving a dose below 15 mg per kg body weight a day for 21 consecutive days were observed to develop vision disorders. A dose of 30 mg/kg body weight administered once

daily for 21 consecutive days led to irreversible damage to sight. A dose of 50 mg/kg body weight administered once daily for 21 consecutive days may cause blindness.

No instances of overdose in dogs, sheep and goats were documented.

No antidote has been identified in case of accidental overdose in these animals, symptomatic treatment should be applied. <u>Major incompatibilities:</u>

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

Target species: cattle (calves), sheep, goat, pig, dog and cat.

Very rare (< 1 animal/10 000 animals treated, including isolated reports)	Gastrointestinal disorders (diarrhoea) ¹
Very rare (< 1 animal/10 000 animals treated, including isolated reports)	Injection site reactions ²
Frequency unknown, cannot be determined on the basis of available data	Inflammatory injection site reactions ³
Frequency unknown, cannot be determined on the basis of available data	Injection site reaction ⁴

¹These signs are usually mild and transient.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product.

If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office

for Registration of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C PL-02-222 Warsaw Tel.: +48 22 49-21-687

Fax: +48 22 49-21-605 https://smz.ezdrowie.gov.pl





² May be observed in calves. The signs may persist for up to 14 days.

³ May be observed in pigs. Inflammation may persist for up to 28 days after injection.

Moderate, transient local reaction (e.g. swelling) may be observed in dogs.





Injection solution intended for dogs, cats, cattle, sheep, goats and pigs (enrofloxacin 50 mg/ml)

Dosage for each target species, route(s) and method(s) of administration

Intravenous, subcutaneous or intramuscular administration.

5 mg of enrofloxacin per kg of body weight, which corresponds to 1 ml per 10 kg body weight once daily for 3 to 5 days.

In case of acute mycoplasma arthritis caused by Mycoplasma bovis susceptible to enrofloxacin: 5 mg of enrofloxacin per kg of body weight, which corresponds to 1 ml per 10 kg body weight once daily for 5 days.

Inject the product slowly, intravenously or subcutaneously. Do not inject subcutaneously more than 10 ml of the product at one site.

Sheep and goats:

5 mg of enrofloxacin per kg of body weight, which corresponds to 1 ml per 10 kg body weight once daily for 3 days.

Inject subcutaneously.

Do not inject more than 6 ml of the product at one site.

2.5 mg of enrofloxacin per kg of body weight, which corresponds to 0.5 ml per 10 kg body weight once daily for 3 days.

In case of gastrointestinal infections or septicaemia caused by Escherichia coli: 5 mg of enrofloxacin per kg of body weight, which corresponds to 1 ml per 10 kg body weight once daily for 3 days.

Inject intramuscularly in the neck, near the base of the ear.

Do not inject more than 3 ml of the product at one site.

5 mg of enrofloxacin per kg of body weight, which corresponds to 1 ml per 10 kg body weight once daily for 5 days.

Inject subcutaneously.

The product may be used to initiate treatment that may be continued with the product in oral dosage form (tablet), administered in accordance with instructions specified in the Summary of Product Characteristics.

Advice on correct administration

In case of multiple injections, rotate injection sites.

To ensure a correct dosage, body weight should be determined as accurately as possible.

Withdrawal period(s)

Meat and offal after intravenous administration – 5 days. Meat and offal after subcutaneous administration – 12 days.

Product not approved for use in animals producing milk intended for human consumption.

Sheep:

Meat and offal - 4 days.

Milk-3 days.

Goats:

Meat and offal - 6 days. Milk - 4 days.

Meat and offal - 13 days.

Special storage precautions

Keep out of the sight and reach of children.

Store in the original package, in order to protect from light. Store below 25°C

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate package: 28 days.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Detailed information on this veterinary medicinal product is available in the Union Product Database

(https://medicines.health.europa.eu/veterinary).

Package size: 100 ml Shelf life: 2 years

For animal use only. Prescription-only veterinary medicine. To be administered under veterinary supervision.

Marketing authorization number: 2985/20 SPC: 2024-09-26









Injection solution intended for cattle and pigs (enrofloxacin 100 mg/ml)

Composition

Each ml contains:

Active substance:

Enrofloxacin – 100 mg

Excipient:

Benzyl alcohol (E-1519) – 157 mg Clear, slightly yellow solution.

Indications for use

Cattle

Treatment of respiratory infections caused by *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma spp.* susceptible to enrofloxacin.

Treatment of gastrointestinal infections caused by *Escherichia coli* susceptible to enrofloxacin.

Treatment of septicaemia caused by *Escherichia coli* susceptible to enrofloxacin.

Treatment of acute mycoplasma arthritis caused by *Mycoplasma bovis* susceptible to enrofloxacin in cattle less than 2 years of age.

Pigs

Treatment of respiratory infections caused by Pasteurella multocida, Mycoplasma spp. and Actinobacillus pleuropneumoniae susceptible to enrofloxacin.

Treatment of urinary infections caused by *Escherichia coli* susceptible to enrofloxacin.

Treatment of Postpartum Dysgalactia Syndrome – PDS (Metritis Mastitis Agalactia MMA) caused by Escherichia coli and *Klebsiella spp.* susceptible to enrofloxacin.

Treatment of gastrointestinal infections caused by *Escherichia coli* susceptible to enrofloxacin.

Treatment of septicaemia caused by *Escherichia coli* susceptible to enrofloxacin.

Contraindications

Do not use as a preventive measure.

Do not use in case of known cross-resistance to fluoroquinolones or quinolones.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Do not use in growing horses due to the risk of joint cartilage damage.

Special warnings

Special precautions for safe use in the target species:

Degenerative changes in joint cartilage were observed in calves treated with 30 mg of enrofloxacin per kg body weight, administered per os for 14 days.

Principles of prudent use:

If possible, fluoroquinolones should be used based on results of antimicrobial resistance testing.

During product use, comply with the applicable national and local guidelines for using antimicrobial drugs.

Fluoroquinolones should be used in treating only those diseases in which observed response to administration of other classes of antimicrobial drugs is not satisfactory or the response to treatment is expected to be insufficient.

Using the product contrary to provisions of the Summary of Product Characteristics may lead to increased frequency of

microbial resistance to fluoroquinolones and decreased efficacy of treatment using other quinolones due to emergence of a potential cross-resistance.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. In case of accidental contact with skin or mucous membranes—immediately flush the affected area with water.

People with known hypersensitivity to enrofloxacin should avoid contact with the veterinary medicinal product.

Pregnancy:

Do not use the product during pregnancy.

Lactation:

Do not use the product during the lactation period.

Interaction with other medicinal products and other forms of interaction:

Do not use the product simultaneously with macrolide antibiotics, tetracyclines and theophylline.

Overdose:

Enrofloxacin displays low toxicity after single-dose administration, and low acute toxicity. LD50 is approx. 4000-5000 mg/kg body weight after per os administration in rats and mice, whereas in rabbits which are more susceptible – 500-800 mg/kg body weight.

After a single-dose administration of a particularly high amount, toxic effects may be manifested by lethargy, tremor, tonic seizures, ataxia and dyspnoea.

Use of enrofloxacin doses exceeding 5 mg/kg body weight may cause vision disorders, retinal degeneration and blindness.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

Target species: cattle, pigs

Very rare

(< 1 animal/10 000 animals treated, including isolated reports)

Developmental changes in cartilage¹

Gastrointestinal disorders¹ Nervous system disorders ¹

¹ Long-term use of high therapeutic doses in growing animals

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the









Injection solution intended for cattle and pigs (enrofloxacin 100 mg/ml)

contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C PL-02-222 Warsaw

Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605

https://smz.ezdrowie.gov.pl

Dosage for each target species, routes and method of administration

Subcutaneous or intramuscular administration.

In case of multiple injections, rotate injection sites.

Cattle

Subcutaneous injection of 5 mg of enrofloxacin per kg of body weight, which corresponds to 1 ml per 20 kg body weight once daily for 3 to 5 days.

In case of acute mycoplasma arthritis caused by Mycoplasma bovis susceptible to enrofloxacin in calves less than 2 years of age: subcutaneous injection of 5 mg of enrofloxacin per kg of body weight, which corresponds to 1 ml per 20 kg body weight once daily for 5 days.

Do not inject subcutaneously more than 5 ml of the product at one site.

Pigs

Intramuscular injection of 2.5 mg of enrofloxacin per kg of body weight, which corresponds to 0.5 ml per 20 kg body weight once daily for 3 days.

In case of gastrointestinal infections or septicaemia caused by Escherichia coli: intramuscular injection of 5 mg of enrofloxacin per kg of body weight, which corresponds to 1 ml per 20 kg body weight once daily for 3 days.

Inject in the neck, near the base of the ear.

Do not inject more than 3 ml of the product at one site.

Advice on correct administration

To ensure a correct dosage, body weight should be determined as accurately as possible.

Withdrawal period(s)

Cattle:

Meat and offal: 12 days.

Milk: 4 days.

Pigs:

Meat and offal: 13 days. **Special storage precautions**

Keep out of the sight and reach of children.

Store below 25°C. Protect from light. Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate package: 28 days.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Detailed information on this veterinary medicinal product is available in the Union Product Database

(https://medicines.health.europa.eu/veterinary).

Package size: 100 ml **Shelf life:** 2 years

For animal use only.

Prescription-only veterinary medicine.
To be administered under veterinary supervision.

Marketing authorization number: 715/99

SPC: 2024-09-26





Enflocyna Sol



Oral solution for pigeons, turkeys, chickens, dogs, cattle and pigs (enrofloxacin 50 mg/ml)

Composition

Each ml contains:

Active substance:

Enrofloxacin – 50 mg

Excipient:

Benzyl alcohol (E-1519) – 15.7 mg Clear, slightly yellow solution.

Target species

Cattle, pigs, dogs, hens, turkeys, pigeons.

Indications for use

The veterinary medicinal product is effective for treating general and local diseases caused by microbes susceptible to enrofloxacin, in particular bacterial infections of respiratory and genitourinary systems, as well as bacterial skin infections, wound infections and secondary infections in viral diseases. It has a broad spectrum of action against Gram-positive bacteria (in particular, *Staphylococcus spp.*, *Streptococcus spp.*), Gram-negative bacteria (in particular *E. coli, Salmonella spp.*, *Pasteurella spp.*, *Klebsiella spp.*, *Pseudomonas spp.*) and *Mycoplasma species*.

Efficacy of enrofloxacin has been confirmed in particular in the treatment of the following diseases in the target species:

<u>Cattle (calves):</u> Treatment of respiratory infections caused by *Klebsiella spp., Pasteurella spp., Mycoplasma spp.*, urinary tract infections caused by *Staphylococcus spp., Klebsiella spp., Pseudomonas spp.*, and gastrointestinal infections caused by *E. coli, Salmonella spp.*

<u>Pigs:</u> Treatment of respiratory infections caused by *Klebsiella spp., Pasteurella spp., Mycoplasma spp.*, urinary tract infections caused by *Klebsiella spp., Pseudomonas spp.*, gastrointestinal infections caused by *E. coli, Salmonella spp.*, MMA syndrome caused by *Staphylococcus spp., Streptococcus spp., E. coli, Klebsiella spp.*

<u>Dogs:</u> Treatment of respiratory infections caused by *Staphylococcus spp., Klebsiella spp., Pasteurella spp., Mycoplasma spp.,* urinary tract infections caused by *E. coli, Klebsiella spp., Pseudomonas spp.,* and gastrointestinal infections caused by *E. coli, Salmonella spp.*

<u>Pigeons:</u> Treatment of systemic infections caused by Staphylococcus spp., Escherichia coli, Salmonella spp., Pasteurella spp., Mycoplasma spp., as well as bacterial infections in viral diseases.

<u>Hens, turkeys:</u> Treatment of infections caused by the following bacteria susceptible to enrofloxacin:

- Hens: Mycoplasma gallisepticum, Mycoplasma synoviae, Avibacterium paragallinarum, Pasteurella multocida.
- Turkeys: Mycoplasma gallisepticum, Mycoplasma synoviae, Pasteurella multocida.

Contraindications

Do not use as a preventive measure.

Do not use in case of confirmed cross-resistance to fluoroquinolones in a herd intended to be treated.

Do not use in small breed dogs less than 8 months of age, in large breed dogs less than 12 months of age, whereas in giant breed dogs less than 18 months of age.

Do not use in calves with developed forestomach.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Special warnings

Special warnings:

Treatment of infections caused by *Mycoplasma spp.* might not eradicate this bacteria completely.

Special precautions for safe use in the target species:

Principles of prudent use:

If possible, fluoroquinolones should be used based on results of antimicrobial resistance testing.

During product use, comply with the applicable national and local guidelines for using antimicrobial drugs.

Fluoroquinolones should be used in treating only those diseases in which observed response to administration of other classes of antimicrobial drugs is not satisfactory or the response to treatment is expected to be insufficient.

Using the product contrary to provisions of the Summary of Product Characteristics may lead to increased frequency of microbial resistance to fluoroquinolones and decreased efficacy of treatment using other quinolones due to emergence of a potential cross-resistance.

Since the initial approval of enrofloxacin for use in poultry, reduced susceptibility of E. coli to fluoroquinolones and emergence of susceptible microorganisms have been observed to spread. Resistance of *Mycoplasma synoviae* has also been reported in the EU.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental contact with skin or mucous membranes – immediately flush the affected area with water.

Pregnancy and lactation:

Do not use during pregnancy and the lactation period. Laying birds:

The product can be used in the laying period.

Interaction with other medicinal products and other forms of interaction:

Do not use the product simultaneously with macrolide antibiotics, tetracyclines and theophylline, in pigeons taking coccidiostatics. Magnesium and aluminium compounds may inhibit absorption of enrofloxacin from the gastrointestinal tract

Overdose:

Enrofloxacin displays low toxicity after single-dose administration, and low acute toxicity. LD_{so} is approx. 4000-5000 mg/kg body weight after per os administration in

rats and mice, whereas in rabbits which are more susceptible – 500-800 mg/kg body weight.

After a single-dose

administration of a particularly high amount, toxic effects may be manifested by lethargy, tremor, tonic seizures, ataxia and dyspnoea.





Enflocyna Sol



Oral solution for pigeons, turkeys, chickens, dogs, cattle and pigs (enrofloxacin 50 mg/ml)

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

Target species: cattle (calves), pigs, dogs, hens, turkeys, pigeons.

Very rare (<1 animal/10 000 animals treated, including isolated reports) Developmental changes in cartilage¹

Gastrointestinal disorders ¹ Nervous system disorders ¹

¹Long-term use of high therapeutic doses in growing animals Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

Al. Jerozolimskie 181C, PL-02-222 Warsaw Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605

https://smz.ezdrowie.gov.pl

Dosage for each target species, route(s) and method(s) of administration

Cattle (calves): 0.05-0.10 ml of the product/kg body weight

for 3 to 5 days.

Pigs: 0.05-0.10 ml of the product/kg body weight

for 3 to 5 days.

<u>Dogs:</u> 0.05-0.10 ml of the product/kg body weight

for 3 to 5 days.

<u>Hens and turkeys:</u> 0.2 ml of the product/kg body weight (corr. to 10 mg of enrofloxacin/kg body weight) daily for 3 to 5 consecutive days.

Administer for 3 to 5 consecutive days; in case of mixed infections or chronic progressive infections, for 5 days. If clinical signs do not alleviate within 2 to 3 days, treatment with alternative antimicrobials should be considered based on the results of susceptibility testing.

Pigeons: 0.1 – 0.4 ml of the product/kg body weight.

Administer the product after dilution in water, assuming that the average daily water intake by 20 pigeons is 1 litre. If the water intake is different, this should be taken into account in dosage.

Salmonellosis: 0.4 ml/kg body weight, corr. to 4 ml/1 litre of water daily for 3 days or 2 ml/1 litre for 7 to 10 days.

Mycoplasmosis, respiratory infection in pigeons: 0.2 ml/kg body weight corr. to 2 ml/litre of water for 4 to 7 days.

Other bacterial infections: $0.1 \, \text{ml/kg}$ body weight, corr. to ml/litre of water for $3 \, \text{to} \, 4 \, \text{days}$.

Advice on correct administration

Prepared solution of the veterinary medicinal product should be used within 24 hours.

Administer the product after dilution in drinking water, milk or milk replacer. Liquids containing the product should be exchanged every 24 hours.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The intake of the prepared solution depends on the clinical condition of the treated animals.

Concentration of the solution should be properly adjusted, in order to obtain a correct dose of the applied antibiotic in the treated animals

Withdrawal period(s)

Meat and offal:

Calves, pigs: 10 days,

Hens: 7 days,

Turkeys: 13 days,

Dogs – not applicable.

Do not use in pigeons intended for human consumption.

Do not use in laying hens from which eggs are produced for human consumption.

Do not use in young birds reared for laying from which eggs are produced for human consumption within 14 days before the start of the laying period.

Special storage precautions

Keep out of the sight and reach of children.

Store below 25°C. Protect from light. Do not freeze.Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate package: 28 days. Shelf life after dilution in drinking water, milk or milk replacer: 24 hours

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Package size: 100 ml Shelf life: 2 years

For animal use only.
Prescription-only veterinary medicine.

To be administered under veterinary supervision.

Marketing authorization: 716/99 SPC: 2024-09-26





Gentamycyna Biowet Puławy



Injection solution intended for dogs and cats (gentamicin 50 mg/ml)

Composition

Active substance:

Gentamicin (gentamicin sulfate) – 50 mg/ml

Excipients:

Sodium pyrosulfate – 3.5 mg/ml Disodium edetate – 1.3 mg/ml Clear. colourless solution.

Target species

Dogs, cats.

Indications

- Respiratory infections caused by Staphylococcus sp., Pseudomonas aeruginosa, Klebsiella sp., Mycoplasma sp.,
- Genitourinary tract infections caused by Staphylococcus sp., Escherichia coli, Pseudomonas aeruginosa, Klebsiella sp., Proteus sp.,
- Gastrointestinal infections caused by Staphylococcus sp., Campylobacter sp., Escherichia coli, Pseudomonas aeruginosa, Salmonella sp.,
- Skin and ear infections caused by Staphylococcus sp., Pseudomonas aeruginosa, Proteus sp.,
- Joint infections caused by Staphylococcus sp., Pseudomonas aeruginosa.

Contraindications

Do not use in pregnant animals.

Do not use in animals with renal failure.

Do not use in animals allergic to aminoglycosides.

Do not use in severely dehydrated animals.

Special warnings

Special warnings:

None.

Special precautions for safe use in the target species:

Young animals in which renal clearance of gentamicin takes more time than in adult animals are more susceptible to the toxic effect of the product.

In animals less than 2 weeks of age, administer half the recommended doses.

Administration of the product should be based on results of antimicrobial resistance testing on isolates from sick animals. If this is impossible, applied treatment should be based on the local epidemiological information concerning drug susceptibility of the isolated bacteria.

If animal condition requires longer administration of the drug, it is recommended to monitor kidney health by controlling serum urea and serum creatinine concentrations.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The product may sensitise the skin leading to development of contact dermatitis. During administration of the product, wear protective clothing and take special precautions. In case of accidental contact with the product, immediately wash away the solution from the surface of skin or mucous membranes. In case of self-injection, hypersensitivity reaction may be elicited. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

<u>Special precautions for the protection of the environment:</u> Not applicable.

Pregnancy and lactation:

Do not use during pregnancy.

Due to the nephrotoxic effect, use caution in the lactation period, only when the benefit for the mother exceeds the potential risk for the newborn animals.

Interaction with other medicinal products and other forms of interaction:

Gentamicin shows cross-resistance to other aminoglycosides. It acts synergistically with β-lactam antibiotics (especially ampicillin and benzylpenicillin) against enterococci, staphylococci and streptococci. Also, it acts synergistically with vancomycin and rifampicin against streptococci and staphylococci. Cephalosporins and some diuretics enhance nephrotoxicity and ototoxicity of the product. Therefore, it cannot be administered in combination with cephalotin, cephaloridine, etacrynic acid, mannitol and furosemide. Its simultaneous use with vancomycin enhances nephrotoxicity of both drugs. A combination with cisplatin reduces gentamicin elimination, thus posing a risk of nephrotoxicity and hypomagnaesemia. The preparation should not be mixed with solutions of broad-spectrum penicillin, as this may lead to inactivation of aminoglycoside. Its simultaneous use with amphotericin B, cyclosporine, cisplatin, methoxyflurane, acyclovir and non-steroid anti-inflammatory drugs may cause kidney damage. In general anaesthesia, gentamicin administered in combination with cyclopropane may cause apnoea.

Overdose:

Gentamicin toxicity may cause renal failure, neuromuscular block or hearing loss. If any of the above-listed signs occur, discontinue administration of the product.

Major incompatibilities:

Do not use simultaneously with other antibiotics, strong diuretics and drugs likely to cause nephrotoxicity and ototoxicity.

Do not administer in combination with anaesthetics or muscle relaxers.

Adverse events

Long-term administration of the product or gentamicin toxicity may lead to kidney or hearing damage. Intrathecal administration may cause inflammation of nerve roots, fever and chronic pleocytosis.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this

package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of





Gentamycyna Biowet Puławy



Injection solution intended for dogs and cats (gentamicin 50 mg/ml)

Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw,

Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605.

https://smz.ezdrowie.gov.pl

Dosage for each target species, routes() and method(s) of administration

Administer the product subcutaneously or intramuscularly in a dose of 0.8 ml/10 kg body weight (which corresponds to 4 mg of gentamicin/kg body weight)

- on the first day of treatment, administer the product every 12 hours
- consecutive days once daily every 24 hours.

Administer the antibiotic for 4 to 5 days, in case of urinary infections—for 7 to 10 days.

Urine alkalinization increases antibiotic activity.

Advice on correct administration

None

Withdrawal period(s)

Not applicable.

Special storage precautions

Keep out of the sight and reach of children.

Store below 25°C. Protect from light. Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label.

Shelf life after first opening the immediate package: 28 days.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Detailed information on this veterinary medicinal product is available in the Union Product Database

(https://medicines.health.europa.eu/veterinary).

Package size: 50 ml Shelf life: 3 years

For animal use only.

Prescription-required veterinary medicine.
Administration under veterinary supervision.

Marketing authorization number: 281/96

SPC: 2023-12-14





ישיאת היותר היה היותר מו

time to heal wounds faster

Hyalsept

Gel that supports the wound healing process in animals (sodium hyaluronate, iodine, potassium iodide)





- facilitates wound healingand tissue regeneration at the wound site
- maintains optimal moisture balance
- protects wounds from infection
- accelerates the process of angiogenesis in damaged tissues



GMP certified quality



EU sourced raw materials



Unique HA structure

Indications

- Slow or difficult healing postoperative wounds and wound dehiscence
- Superficial and deep wounds of various origins
- Extensive abrasions and injuries
- Trauma-related wounds and contusions
- Lesions caused by bites

Properties

Hyalsept promotes wound healing by forming a protective barrier that isolates the wound from external environmental factors while maintaining optimal moisture levels. The gel formulation ensures maximum adhesion, allowing active substances to adhere to the wound, keeping it hydrated and facilitating healing, while also preventing dressing adhesion. **Sodium hyaluronate** promotes wound healing and tissue regeneration. **Iodine** and **potassium iodide** have disinfecting properties.

Method of application

For external use only, applied topically to the wound.

Remove Hyalsept from refrigeration before use and allow it to reach room temperature.

Maintain hygiene during application.

After cleansing the wound and removing fur, apply the appropriate amount of the product onto the wound or a sterile dressing using a sterile syringe.

For small wounds

(Up to 2 cm in diameter): Apply approximately 2 ml of Hyalsept directly onto the wound. Then, cover the wound with a sterile dressing.

For medium wounds

(Up to 7 cm in diameter): Apply approximately 5 ml of Hyalsept onto a sterile dressing. Place the gel-soaked dressing onto the wound and cover it with an additional sterile dressing.

For large wounds

(Up to 10 cm in diameter): Apply approximately 8 ml of Hyalsept onto a sterile dressing. Place the gel-soaked dressing onto the wound and cover it with an additional sterile dressing.

If the dressing adheres to the wound, moisten it before removal, e.g., with a saline solution.

Packaging

Glass bottle containing 50 ml or 20 ml of Hyalsept, equipped with a cannula for multiple extractions of the gel, packed in a cardboard box.

Shelf life: 24 months

Leaflet preparation date: 2024-03-22



immune system boost



Immunex complex

Immunity-enhancing powder for pigeons and ornamental birds (yeast rich in beta-1,3/1,6-D-glucan, vitamins A, C, and E, calcium, phosphorus, glucose, extracts of echinacea purpurea and grapes)





- replenishes macro- and microelements
- comprehensive formula including:
 - beta-1,3/1,6-D-Glucan
 - glucose and vitamins C, E, and A
 - brewer's yeast (Saccharomyces cerevisiae)
 - grape seed and echinacea purpurea extract

Composition per 100 g

dried brewer's yeast 25.0 g, dicalcium phosphate 20.8 g, glucose 19.0 g

Dietary additives / Vitamins per kg

Vitamin C (3a300) – 250,000 mg

Vitamin E (3a700) – 7,710 mg

Vitamin A (3a672a) – 5,074 mg

Sensory additives per kg

echinacea purpurea extract (2b) – 50 g

dried grape extract (2b485) - 170 g

Analytical constituents / Trace elements per 100 g

calcium 5,510 mg, phosphorus 3,600 mg

Analytical Constituents

crude ash 19.2%, moisture content 4.4%, crude protein 4.1%, crude fat 1.1%, crude fiber -0.4%

Properties

Immunex Complex contains yeast rich in beta-1,3/1,6-D-glucan, which supports immune system function. Vitamins C and E, along with grape extract, serve as powerful antioxidants. Vitamin A plays a crucial role in the visual and reproductive systems. Echinacea purpurea strengthens immune defenses. Calcium and phosphorus contribute to bone health, while glucose provides a primary energy source.

Indications

- during weakened immunity
- as supportive therapy in viral, bacterial, and parasitic diseases
- during recovery from illness
- pre- and post-vaccination support
- during chick rearing
- before flights, exhibitions, and transport

Immunex Complex is especially recommended for young pigeons and racing pigeons during periods requiring peak performance.

Dosage and administration

Administer 2 g (flat teaspoon) per 1 kg of feed, moistened with a small amount of oil or water with honey.

Supportive use:

- -during infections daily and for 3 days post-treatment
- before vaccination, flights, exhibitions, and travel for 14 consecutive days
- $-during\,chick\,rearing\,-\,for\,7\,days$

Preventive use:

- daily for 14 days

Note: If diarrhea has been present in the flock, do not use oil for feed moistening.

A minimum 2-week break is recommended before resuming supplementation.

Storage conditions

Store at room temperature in the original, tightly sealed packaging. Protect from light and moisture.

Package size: 250 g doypack sachet

Shelf life: 2 years

Complementary feed mixture for pigeons and ornamental birds.

 $Veterinary\ identification\ number: \alpha PL0614003p$

Leaflet preparation date: 2024-11-29



Injectio Glucosi 40% 🔊



Injection solution intended for horses, cattle, pigs, sheep, goats, dogs and cats (glucose monohydrate 400 mg/ml)

Active substance and excipient content

Glucosum monohydricum 400 mg/ml

Therapeutic indications

- Supplementation of energy deficiency.
- Hypoglycaemia and ketosis treatment.
- As a diuretic preparation.
- Supportive in liver diseases treatment.

Contraindications

- Hyperglycaemia
- Water intoxication
- · Hypotonic dehydration and acidosis.

Adverse reactions

Rapid or prolonged administration of glucose solution might increase diuresis and cause tissue dehydration and water electrolyte disorders, including hypoglycaemia.

Administration of glucose as the only fluid might lead to development of hypervolemia, hypoosmia and electrolyte imbalance. Parenteral administration of glucose solutions requires administration of potassium, magnesium and phosphates. Too rapid administration of glucose might cause pulmonary oedema. The product displays an irritating effect and may cause pain at the injection site. Administered into peripheral vessels, it causes local thrombotic and inflammatory lesions. Administration of the product with a temperature lower than body temperature might cause irritation and thrombophlebitis at the injection site. Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from https://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Posology per each species, routes and methods of administration

Administer the product slowly intramuscularly in the following doses:

Animal species	Glucose in substance	INJECTIO GLUCOSI 40%
Cattle, horses	100,00 – 125,00 g	250,0 – 312,5ml
Sheep, goats, pigs	12,50 - 25,00 g	31,0 – 62,5 ml
Dogs, cats	1,25 – 7,50 g	3,0 - 19,0 ml

Recommendations for proper administration

The solution should be warmed to body temperature before intravenous use.

Recommended glucose administration rate: 0.5 g/1 kg b.w./1 hour.

Once the container is opened, the product cannot be stored and used again. If visually detectable changes in the solution or damage to the package occur, the product should not be used.

Withdrawal period

Dogs, cats – not applicable Cattle, horses, sheep, swine, goats Edible tissues – zero days Milk – zero days.

Special precautions for storage

Keep out of the sight and reach of children.

Do not use after the expiry date given on the label.

Store at a temperature below 25°C. Protect from sunlight. Do not freeze

Durability after the first opening of the immediate package – use the content of the package all at once.

Special warnings

Special precautions for use in animals

During administration of glucose solution, proper infusion rate should be maintained. Too rapid or prolonged administration might cause tissue dehydration and water electrolyte disorders.

In diabetic patients, administer glucose only in the case of lifethreatening hypoglycaemia induced by insulin overdose.

Use with caution in animals with adrenal insufficiency and in anuria.

During a long-lasting use, fluid balance, concentration of electrolytes and acid-base balance should be monitored.

Special precautions for persons administering the medicinal veterinary product to animals:

Caution should be taken to avoid self-injection.

Glucose might cause serious physiological changes which are dangerous to a pregnant female and foetus. Therefore, the product should not be used in pregnancy except in absolute necessity and with particular caution.

No contraindications for use in lactation.

Glucose overdose causes hyperglycaemia and osmotic diuresis, which in consequence leads to cellular dehydration.

In the case of overdose, apply symptomatic treatment.

In physiological conditions, glucose present at excessive concentrations in the circulatory system after reaching the renal threshold is excreted through the kidneys. A healthy body is capable of maintaining glucose homeostasis and, as a result of polydipsia and polyuria, maintain the correct glucose level

Glucose should not be combined in solutions with barbiturates, sulphonamides, erythromycin, hydrocortisone and vitamin B_{12} .

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Available containers: 250 ml

Shelf life: 2 years

For animal treatment only.

Subject to medical prescription – prescription drug.

Tobe administered under veterinary supervision.

Marketing authorization: 752/99 SPC: 2015-05-07



Injectio Pyralgini Biowet Puławy



Injection solution intended for horses, cattle, pigs and dogs (metamizole sodium 500 mg/ml)

Active substance and excipient content

1 ml contains:

Active substance:

Metamizole sodium 500 mg

Excipient:

Sodium pyrosulphate 0.9 mg

Therapeutic indications

Metamizole sodium displays analgesic, spasmolytic, antipyretic and anti-inflammatory effects.

Indications for the use of the drug:

- Pain relief in colic of various aetiology or in other spastic diseases of the gastrointestinal tract in horses and cattle.
- Equine paralytic myoglobinuria.
- Obstruction of the oesophagus with a foreign body.
- Conditions with fever such as mastitis, MMA (Mastitis Metritis Agalactia) syndrome in swine, swine influenza.
- Acute arthritis, rheumatic conditions of the musculoskeletal system, neuritis, neuralgia, tendinitis and inflammation of tendon sheaths.

Contraindications

- Do not use in cats.
- Do not use in animals with disorders of the haematopoietic system.
- Do not use in animals with renal insufficiency and asthma.
- Do not use in the case of hypersensitivity to the active substance or the excipient.

Adverse reactions

Fast intravenous administration may cause shock.

Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from https://www.urpl.gov.pl (Department of Veterinary Medicinal Products)

Amount to be administered per species, method and route of administration

The drug should be administered intramuscularly or in a slow intravenous infusion.

In horses whose tissues are intended for human consumption, the drug should only be administered intravenously.

The drug can be administered again after 8 hours.

Posology:

Species	Metamizole sodium dose	Product dose
Horses	20-50 mg/kg b.w.	0,4 - 1,0 ml/10 kg b.w.
Cattle	20-40 mg/kg b.w.	0,4 - 0,8 ml/10 kg b.w.
Pigs	15-50 mg/kg b.w.	0,3 - 1,0 ml/10 kg b.w.
Dogs	20-50 mg/kg b.w.	0,4 - 1,0 ml/10 kg b.w.

Indications for proper administration

In order to properly administer the product, instructions in this leaflet should be followed.

Withdrawal period

Horses

 $Edible\ tissues: 12\ days\ after\ the\ intravenous\ administration.$

In horses whose tissues are intended for human consumption, the drug should only be administered intravenously.

Cattle:

Edible tissues: 12 days after the intravenous administration 20 days after the intramuscular administration

Milk: 24 hours

Pigs:

Edible tissues: 12 days after the intravenous administration 20 days after the intramuscular administration

<u>Dogs:</u> not applicable.

Special precautions for storage

Store in the original container in order to protect from light. Store at a temperature below 25°C.

Do not use this veterinary medicinal product after its expiry date given on the label.

Shelf life after first opening of the immediate container – 28 days

Special warnings

Special precautions for use in animals:

Do not use subcutaneously – metamizole may irritate the subcutaneous tissue.

Special precautions for people administering veterinary medicinal product to animals:

Caution should be taken to avoid accidental self-injection. In rare cases, metamizole can cause reversible but potentially life-threatening agranulocytosis or other reactions such as skin allergies. Persons with diagnosed hypersensitivity to pyrazolones or aspirin should avoid contact with the product.

In the case of accidental self-injection, immediately seek medical advice and show the package leaflet or the label to the physician.

Pregnancy:

The product can be used in pregnancy.

Lactation:

The product can be used during lactation.

<u>Interactions with other medicinal products or other forms of interaction</u>

Phenobarbital, other barbiturates and glutethimide can accelerate metamizole elimination. Simultaneous administration of chlorpromazine may lead to the occurrence of severe hypothermia

Overdose (symptoms, emergency procedures, antidotes):

No specific symptoms of overdosage are known.

Pharmaceutical incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines





Injectio Pyralgini Biowet Puławy



Injection solution intended for horses, cattle, pigs and dogs (metamizole sodium 500 mg/ml)

no longer required. These measures should help to protect the environment.

Other information

For more information about this veterinary medicinal product, contact the Marketing Authorization Holder.

Available containers:

50 ml, 100 ml **Shelf life:** 2 years

For animal treatment only. Subject to medical prescription – prescription drug. To be administered only by a veterinary surgeon.

Marketing authorization number: 201/95 SPC: 2021-10-04









Powder for cutaneous use for dogs and pigeons (permethrin - as cis/trans 25:75 - 10 mg/g)

Active substance

Permethrin (as permethrin cis/trans 25:75) 10 mg/g

Therapeutic indications

Insectin is intended for the control of ectoparasite infestations: fleas and ticks in dogs, as well as lice and soft ticks in pigeons.

Contraindications

Do not use in puppies under 12 weeks of age.

Do not use in lactating females.

Do not use in pigeons under 1 month of age.

Do not use in cats. This product may cause severe adverse reactions in cats, including fatal outcomes; therefore, any contact with the product must be avoided. If dogs and cats are kept together, they must be separated for 72 hours following treatment. Ensure that cats do not lick the fur of a treated dog. If this occurs, seek veterinary assistance immediately.

Do not use in cases of hypersensitivity to the active substance or any excipient.

Adverse reactions

In dogs, adverse reactions are rare and may include excessive salivation, vomiting, diarrhea, mild muscle tremors, and hyperactivity progressing to depression.

Birds have low sensitivity to permethrin. Adverse reactions affecting the nervous system are exceptionally rare.

If any adverse reactions occur after using this product, or if any unusual symptoms not listed in this leaflet are observed (including reactions in humans due to contact with the product), report them to the appropriate veterinarian, the responsible entity, or the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products. The reporting form can be downloaded from

https://www.urpl.gov.pl(Veterinary Medicinal Products Division).

Dosage for each species and method of administration

Small dogs: 5–10 g Medium dogs: 10–15 g Large dogs: 15–20 g Pigeons: 1–2 g

Ten applications (shakes of an inverted container) deliver approximately 2.5–3.0 grams of the product onto the skin.

Instructions for proper use

This product is for external use only.

Sprinkle the product over the entire body of the animal, parting the fur or feathers to reach the skin. Avoid dusting around the eyes, ears, nose, and mouth. Leave the product on for several hours, then brush the fur.

]After each treatment, replace the animal's bedding. Repeat the treatment every 2–3 weeks.

Withdrawal period

Dogs - not applicable.

Do not use in pigeons intended for human consumption.

Special precautions for storage

Keep out of sight and reach of children.

Store in a dry place at a temperature below 25°C.

 ${\it Keep away from human food and animal feed}.$

Do not use this veterinary medicinal product after the expiry date indicated on the label. The expiry date refers to the last day of the specified month.

Special warnings

For each target species:

For external use only.

Do not rub the product into the animal's skin.

To maximize flea eradication, use an appropriate insecticidal treatment in the animal's environment (disinfect bedding, kennels, etc.). It is also recommended to treat all animals kept together.

Precautions for use in animals:

Prevent licking of the product.

Protect the animal's eyes during application.

Precautions for individuals administering the veterinary medicinal product:

The treatment should be carried out outside of living quarters. Avoid excessive dust formation and inhalation of the product. Use general precautions when handling ectoparasiticides, including wearing gloves and protective masks. Avoid contact with eyes. Wash hands after application. If accidental contact occurs with skin or mucous membranes, rinse the affected area immediately with clean water.

Keep children away from treated animals.

Do not allow treated animals to interact with humans, especially children, until the product is removed from their coat

Individuals with known hypersensitivity to permethrin should avoid contact with the product.

Other precautions:

Treated dogs should not be allowed to swim in bodies of water for at least three weeks after application.

Pregnancy and Lactation

 $Do \ not \ use \ during \ pregnancy \ or \ lactation.$

Laying Period

Do not use in laying birds.

Interactions with Other Medicinal Products and Other Forms of Interaction

None known.

<u>Overdose (Symptoms, Emergency Procedures, Antidotes, if</u> necessary)

In case of overdose, intensive symptomatic treatment should be implemented, as there is no specific antidote.

It is recommended to administer sedative, anticonvulsant (diazepam, pentobarbital, propofol), and muscle relaxant medications.

Fluid therapy with crystalloid solutions (physiological saline or multi-electrolyte solutions) is advised.

Affected animals should be bathed in lukewarm water with mild detergents to remove any residual permethrin from the

Pharmaceutical Incompatibilities

As compatibility studies have not been conducted, this veterinary medicinal product must not be mixed with other veterinary medicinal products.







Powder for cutaneous use for dogs and pigeons (permethrin - as cis/trans 25:75 - 10 mg/g)

Special Precautions for Disposal of Unused Veterinary Medicinal Products or Waste Derived from Such Products

This veterinary medicinal product is highly toxic to bees, fish, and crustaceans.

Do not dispose of medicinal products via wastewater or household waste.

Consult a veterinarian for proper disposal methods to help protect the environment.

Additional Information

For further information on this veterinary medicinal product, please contact the responsible entity.

Package Size: 50 g Shelf Life: 2 years

For animal use only.

Available without a veterinary prescription – OTC.

To be administered by the animal's owner or caregiver.

Marketing authorization number: 742/99 SPC: 2015-02-02













Ketamina Biowet Puławy



Injection solution intended for dogs and cats (ketamine 100 mg/ml)

Composition

Each ml contains

Active substance:

Ketamine – 100 mg

(ketamine hydrochloride – 115.34 mg)

Excipient:

Chlorobutanol hemihydrate – 3 mg

Clear, colourless liquid.

Indications for use

Short-lasting general anaesthesia for minor surgeries requiring analgesia, such as: removal of tartar, removal of foreign bodies from the oral cavity and the oesophagus, incision of abscesses, dressing change, x-ray examinations, clinical examinations of aggressive and excitable animals.

Long-lasting general anaesthesia in combination with other anaesthetics to induce general anaesthesia, for example in operations of fractures, reduction of dislocation, castration, amputation, caesarean section, laparotomy.

Contraindications

Do not use in animals with circulatory failure, hypertension, liver or kidney damage.

Do not use in animals with epilepsy, ocular hypertension, open globe injuries and head injuries.

Do not use in case of hypersensitivity to ketamine or chlorobutanol.

Special warnings

Special warnings:

Do not give any food to animals within 12 hours before administration of the product.

Abdominal surgeries require administration of appropriate analgesics, as ketamine does not relieve visceral sensations.

As ketamine does not eliminate laryngeal reflex, increases salivation and tracheobronchial secretion in procedures on the nasopharynx, larynx, trachea and bronchi, as well as in endoscopy, the product should be used in combination with agents relieving the aforementioned effects of ketamine.

Special precautions for safe use in the target species:

Ketamine may increase salivation and airway secretions, which may lead to choking and airway obstruction.

During anaesthesia, remember to protect eyes against drying of the cornea.

During recovery of animals anaesthetised using ketamine, the following symptoms might occur: hallucinations, delirium, ataxia, hypersensitivity to touch, hyperreactivity, aggression. During recovery, animals should be provided with peace and quiet and protection against self-mutilation.

In case of excessive loss of blood, the ketamine dose should be reduced.

As ketamine increases the heart rate and myocardial oxygen demand, it must be used with caution in patients with cardiomyopathy.

Ketamine causes moderate respiratory depression, frequently reduces the respiratory rate and respiratory volume. After ketamine administration, a characteristic type of respiration occurs involving long periods of apnoea after intake of breath. Therefore, during anaesthesia, cardiovascular and pulmonary function should be monitored.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This veterinary medicinal product is a highly potent drug. Special caution should be taken to avoid self-injection. In case of accidental self-injection, the person administering the product may experience analgesia, and after approximately 10 minutes loss of consciousness persisting for 10 to 15 minutes. Upon recovery, the person may experience amnesia and hallucinations. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive. In case of contact with skin or mucous membranes, flush the affected area with water immediately.

Pregnancy:

Do not use in pregnant animals, except during the caesarean section procedure.

Lactation:

Do not use during the lactation period.

Interaction with other medicinal products and other forms of interaction:

Xylazine, detomidine, medetomidine, acepromazine prevent seizures that may accompany ketamine-induced anaesthesia. Ketamine action is enhanced by other agents that weaken the function of the central nervous system.

Narcotic agents, barbiturates, diazepam may prolong recovery.

Chloramphenicol may prolong the anaesthetic action of ketamine

Neuromuscular blockers, e.g. succinylcholine and tubocurarine, may enhance or prolong respiratory depression.

Thiopental prevents ketamine-induced brain metabolism and dilation of cerebral vessels.

Atropine prevents excessive salivation after ketamine administration.

Overdose:

Exceeding the recommended doses induces respiratory depression. A dose eight times the recommended dose causes respiratory paralysis, whereas a dose twelve times the recommended dose leads to circulatory arrest.

Administration of excessively high doses of the drug might induce vomiting and muscle tremor.

In case of an overdose, mechanical resuscitation methods should be considered – maintain respiration and do cardiac massage.

Special restrictions for use and special conditions for use:

The product is intended to be administered only by a veterinarian.

Major incompatibilities:

Do not use ketamine simultaneously with barbiturates due to their chemical incompatibility.





Ketamina Biowet Puławy



Injection solution intended for dogs and cats (ketamine 100 mg/ml)

Adverse events

Very rare (< 1 animal/10 000 animals treated, including isolated reports):	Respiratory depression ¹ , pulmonary oedema Hypertension, tachycardia, cardiac arrest Seizures
Frequency unknown (cannot be determined on the basis of available data):	Increased muscle tension, spasticity, tonic muscle contractions Increased salivation, vomiting Mydriasis, nystagmus, loss of the palpebral reflex ² Vocalisation ³

¹ moderate

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605

, https://smz.ezdrowie.gov.pl.

Dosage for each target species, route(s) and method(s) of administration

 $In tramuscular\, or\, in travenous\, administration.$

Before administration of ketamine, use premedication by injecting atropine in a dose of 0.05 mg/kg body weight intramuscularly or subcutaneously.

Dogs:

- 2–5 mg of ketamine/kg body weight intravenously
- 5–15 mg of ketamine/kg body weight intramuscularly Cats:

• 5–15 mg of ketamine/kg body weight intramuscularly Administration of ketamine simultaneously with other anaesthetics and premedication agents before general anaesthesia:

Cats administer atropine in a dose of 0.05 mg/kg body weight by intramuscular injection, followed by xylazine or diazepam, and after a few minutes ketamine in a dose of 5–15 mg /kg bodyweight

Dogs administer atropine in a dose of 0.05 mg/kg body weight by intramuscular injection, followed by an antipsychotic (diazepam, medetomidine or xylazine), and after 5 to 10 minutes ketamine in a dose of 3 mg /kg body weight intravenously, or 10 mg/kg body weight intramuscularly.

Onset of general anaesthesia will start after 3 to 5 minutes following intramuscular injection. Ketamine action usually lasts for 20 to 45 minutes. The higher the dose, the longer the duration of anaesthesia.

Dose size does not impact anaesthetic depth.

Majority of animals are able to get up after approximately 2 hours.

Advice on correct administration

In case of intravenous administration, warm the veterinary medicinal product to body temperature and inject slowly.

Withdrawal period(s)

Not applicable

Special storage precautions

Keep out of the sight and reach of children.

Store below 25 °C.

Protect from light.

Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate package: 28 days

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Package sizes: 10 ml, 50 ml

Shelf life: 2 years

Shelf life after first opening of the immediate packaging: 28 days

For animal use only.

Prescription-only veterinary medicine.
To be administered exclusively by a veterinarian.

Possession and distribution of the product are regulated by laws concerning narcotic drugs and psychotropic substances.

Marketing authorization number: 319/97 SPC: 2024-12-31





² may lead to dryness of the cornea

³ may occur during emergence

Lydium-KLP™



Injection solution intended for cattle, horses, and pigs (lysozyme dimer 5 mg/10 ml)

Composition

10 ml of the solution contains:

Active substance: lysozyme dimer 5.0 mg

Preservative: thiomersal 1.0 mg Transparent, colourless solution.

Indications for use

Horses: To support treatment of bacterial and viral infections, in particular gastrointestinal and respiratory inflammations, as well as skin and outer ear inflammations.

<u>Cattle:</u> To support treatment of bacterial and viral infections, in particular gastrointestinal and respiratory inflammations, as well as mammary gland, skin and outer ear inflammations.

<u>Pigs:</u> To support treatment of bacterial and viral infections, in particular gastrointestinal and respiratory inflammations, as well as skin and outer ear inflammations, and MMA (mastitis metritis agalactia).

Contraindications

None

Adverse reactions

None known.

Any adverse reactions emerged after administration of the product or any symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products.

The report form should be downloaded from

https://www.urpl.gov.pl

(Department of Veterinary Medicinal Products).

Dosage for each species, route and method of administration

Horses:

0.02 mg of lysozyme dimer/kg bodyweight (1 ml of the product/25 kg bodyweight) single intramuscular, subcutaneous or intravenous injection.

During concurrent use with antibiotics, 0.01 mg of lysozyme dimer/kg bodyweight (1 ml of the product/50 kg bodyweight) single intramuscular, subcutaneous or intravenous injection.

0.02 mg of lysozyme dimer/kg bodyweight (1 ml of the product/25 kg bodyweight) single intramuscular, subcutaneous or intravenous injection.

During concurrent use with antibiotics, 0.01 mg of lysozyme dimer/kg bodyweight (1 ml of the product/50 kg bodyweight) single intramuscular, subcutaneous or intravenous injection. <u>Pigs:</u>

0.02 mg of lysozyme dimer/kg bodyweight (1 ml of the product/25 kg bodyweight) single intramuscular, subcutaneous or intravenous injection. During concurrent use with

antibiotics, 0.01 mg of lysozyme dimer/kg bodyweight (1 ml of the product/50 kg bodyweight) single intramuscular, subcutaneous or intravenous injection.

Advice on correct administration

None

Withdrawal period

Zero days.

Special precautions for storage

Keep out of the reach and sight of children. Store below 20°C. Do not freeze. Shelf life after first opening the immediate packaging – once opened, use immediately. Do not use after the expiry date stated on the label and outer package.

Special warnings

<u>Special precautions to be taken by the person administering</u> the veterinary medicinal product to animals:

Do not eat, drink or smoke while administering the product. Wash hands after each administration of the product.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been assessed in pregnant and lactating animals. Use only following the benefit-risk assessment performed by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Multiple electrolytes injections administered intravenously with lysozyme dimer may reduce its efficacy. Corticosteroids may interact with lysozyme dimer. For this reason, a 3 hour break should be made between injection of Lydium-KLP and multiple electrolytes or corticosteroid administration.

Major incompatibilities:

None known.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via waste water or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help protect the environment.

Other information

For further details regarding this veterinary medicinal product, please contact the marketing authorization holder.

Package size: 5 glass bottles in a cardboard box

Shelf life: 4 years

Marketing authorization number: 956/99

SPC: 2019-05-07







...prevents, protects and cares



Mastiprewent

Udder care ointment for cows and goats (eucalyptus oil, camphor, menthol, eucerin, yellow petroleum jelly)



- prevents cracking and dryness of the udder and teats
- maintains proper udder elasticity
- spreads easily and provides effective coverage of the udder and teats
- contains plant-derived ingredients: eucalyptus oil, camphor, menthol, eucerin, and petroleum jelly

Composition

Eucalyptus oil, camphor, menthol, eucerine, yellow petroleum jelly.

Indications and usage

The product is recommended for the care of udders in cows and goats.

It is applied externally after each milking by coating and then massaging it into the skin of the udder and teats. Regular use ensures proper elasticity and prevents drying and cracking of the udder and teat skin. Due to its properties, it can also be used for inflammatory conditions caused by insect bites, eczema, abrasions, etc.

Contraindications

Avoid direct contact of the product with mucous membranes. **Storage conditions**

Store at a temperature not exceeding 25°C.

Protect from light. Keep out of sight and reach of children.

Shelf life: 24 months **Packaging size:** 500 g

Leaflet Preparation Date: 2015-11-09





Mentol cools and reduces the sensitivity of pain receptors



Camphor provides antiseptic and warming effects



quick milk diagnosis



Mlek-test®

Diagnostic tool for detecting elevated somatic cell counts and assessing the pH of raw milk





- enables evaluation of milk acidity pH of milk stored in a tank
- helps detect subclinical and clinical udder inflammations
- allows determination of somatic cell count levels starting from 400,000 per 1 ml of milk

Composition

Sodium alkane sulfonate, bromocresol purple, distilled water **Intended use**

Mlek-test is an in vitro diagnostic tool used in veterinary medicine. It is designed to test samples of milk taken from animal body to diagnose and control physiological status or pathological conditions.

Directions for use

- 1. After disposal of the first streams of milk, milk portions of about 2 ml should be squirted onto the tray containing four circular pools. Any excessive milk may be decanted by tipping the tray at an angle of about 50°. Add equal volumes of Mlek-test and the formula and mix thoroughly by swirling the tray. After mixing for about 20 seconds, estimate the degree of thickening and colour change according to the table below.
- 2. Mlek-test also allows determining approximate acidity of milk stored in tank. To that end, mix equal volumes of milk and the formula on the tray. Check the colour of the mixture with the attached colour scale. The mixture of the formula and milk of proper acidity should become greyish-violet. Any possible acidification of the milk gives a greyish-green to yellow colour (depending on acidity)

alkaline milk	normal milk	slightly acidic milk	acidic milk

RESULT	APPEARANCE OF MIXTURE	CELL COUNT in 1 ml
Negative*	Liquid or tufts and trails vanishing during mixing. Greyish-violet.	Up tp 400 000
Positive*	Jelly-like tufts and trails not vanishing during mixing. Greyish-violet or violet.	Up to 1 000 000
Strongly Positive	Mixture becomes jelly-like mass. Violet or dark violet.	Over 1 000 000

* homogenous liquid mixture during the entire mixing period indicates that the somatic cell count does not exceed 200 000 in 1 ml

High somatic cell count (positive result) is usually indicative of mastitis

High somatic cell count in milk for physiological reasons is indicative of oestrus, the colostric period and the dry period.

Storage

Store at below 25° C.

Warnings

Do not freeze!

Keep out of the reach and sight of children.

User precautions

In case of skin or eye contact flush the affected site with profuse amount of water.

Available containers: 500 ml bottles

Shelf life: 18 months

For veterinary use.

Leaflet preparation date: 2015-11-09



Morbital



Injection solution intended for dogs and cats (pentobarbital sodium 133.3 mg/ml, pentobarbital 26.7 mg/ml)

Composition

Each ml contains:

Active substances:

Pentobarbital sodium 133.3 mg Pentobarbital 26.7 mg

Clear, colourless solution.

Target species

Dogs, cats

Indications for use

Product intended for use in euthanasia of dogs and cats.

Contraindications

Not for intrapulmonary, intrapleural and intramuscular administration

Do not use for anaesthesia.

Do not use in animals from which meat and offal are intended for human consumption.

Special warnings

Special precautions for safe use in the target species:

In case of accidental administration of the product to animals not intended for euthanasia, begin ventilation, administer oxygen and analeptics immediately.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Persons with known hypersensitivity to barbiturates should avoid contact with the veterinary medicinal product.

When handling the product, use caution to avoid direct contact. If inhaled, go to fresh air immediately. In case of contact with skin, wash the affected area with soap and water and change clothes, if contaminated with the product. In case of contact with eyes, wash immediately with plenty of water and consult a physician. After ingestion, subcutaneous or intramuscular injection, the product begins to be rapidly absorbed. In case of ingestion or parenteral administration, always seek medical advice immediately and show the package leaflet to the physician. Due to possible sedation, difficulty breathing and blood pressure fluctuations, the person exposed to the product should not drive motor vehicles and always stay under care of others.

To the physician

Pentobarbital concentration in the product is high enough to produce a serious effect on the central nervous system in an adult after injection or ingestion of 2.5 ml of the product. One gram of pentobarbital (which corresponds to less than 7 ml of the product) may be lethal for humans. In case of exposure to the veterinary medicinal product, symptomatic treatment should be applied in order to sustain the basic vital signs.

Other precautions:

Consumption of meat from animals euthanised using this product is dangerous. It may result in deep anaesthesia or death. This also applies to heat treated meat, as barbiturates are resistant to high temperatures. For this reason, carcass of euthanised animals must not be destined for ingestion by other animals, but they should be disposed of in accordance with applicable regulations.

Pregnancy:

If used in pregnant bitches and queens, the death of the mother causes the death of the foetus.

Interaction with other medicinal products and other forms of interaction:

Barbiturates enhance the inhibitory action of d-tubocurarine and hexamethonium on neurotransmission in the motor end plate. What is more, pentobarbital and streptomycin interact to induce significant vasodilation, mainly of kidney vessels. Intravenous injection of calcium solution cancels vasodilating effect, allowing the use of sodium pentobarbital in animals treated with streptomycin. Interactions with some aminoglycosides have also been confirmed.

Overdose:

Not applicable.

Special restrictions for use and special conditions for use:

For administration only by a veterinarian.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

Frequency unknown (cannot be determined on the basis of available data):	Agitation.¹ Dyspnoea.

¹ Transient reaction.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warszawa, Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605

Dosage for each target species, route(s) and method(s) of administration

Intravenous injection is the recommended route of administration.

Intraperitoneal administration is allowed when intravenous injection is impossible or dangerous.

Intracardiac administration is allowed only upon prior

elimination of pain or loss of

https://smz.ezdrowie.gov.pl.

consciousness.

In case of rapid administration (preferably intravenous), the animal falls asleep without any adverse effects. Respiratory and cardiac arrest occur within a dozen or so seconds. Corneal reflex may persist for up to 90 seconds.





Morbital



Injection solution intended for dogs and cats (pentobarbital sodium 133.3 mg/ml, pentobarbital 26.7 mg/ml)

Dosage:

	Morbital	Pentobarbital natrium	Pentobarbital
Intravenous administration	0.3-0.6 ml/kg b.w.	39.99–79.98 mg/kg b.w.	8.01-16.02 mg/kg b.w.
Intraperitoneal administration	1.0-2.0 ml/kg b.w.	133.3-266.6 mg/kg b.w.	26.7-53.4 mg/kg b.w.
Intracardiac administration	0.3-0.6 ml/kg b.w.	39.99–79.98 mg/kg b.w.	8.01-16.02 mg/kg b.w.

Advice on correct administration

The preferred route of administration, involving the smallest and shortest possible pain, is intravenous injection.

In case when intravenous administration is impossible or dangerous, intraperitoneal administration is allowed. This route of administration allows for slow induction of sedation and anaesthesia in animals, therefore they should be provided with peace and quiet.

In fearful, aggressive or wild animals, premedication is recommended. Intracardiac administration is allowed only in exceptional cases, that is in fully sedated, unconscious and deeply anaesthetised animals.

The product should be injected at a fixed pace, with optimum doses administered rapidly. Administration of a deficient dose may induce signs of prolonged sleep with potential awakening.

Before the procedure, animal body weight should be determined as accurately as possible. Smaller doses per 1 kg of body weight are more effective in adult, ill and starving dogs.

In any case, make sure that death of an animal has been obtained indeed, as deep anaesthesia may give the appearances of death.

Withdrawal period(s)

Not applicable.

Special storage precautions

Keep out of the sight and reach of children.

Store below 25°C.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate package: 28 days.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Detailed information on this veterinary medicinal product is available in the Union Product Database

(https://medicines.health.europa.eu/veterinary).

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Biowet Puławy Sp. z o.o.

Henryka Arciucha 2

24-100 Puławy

Poland

Tel./Fax: +48 (81) 886 33 53, Tel.: +48 (81) 888 91 00

e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:

Biowet Puławy Sp. z o.o.

Henryka Arciucha 2

24-100 Puławy

Poland

Tel: + 48 (81) 888 91 33, + 48 509 750 444

e-mail: biowet@biowet.pl

Classification of veterinary medicinal products

 $\label{thm:product} \textbf{Veterinary medicinal product subject to prescription}.$

Pack size: 100 ml

Marketing authorisation number: 651/99

SPC: 2024-11-26





Morbital Plus



Injection solution intended for cattle, horses, pigs, dogs and cats (pentobarbital sodium 400 mg/ml)

Composition

Each ml contains:

Active substance

Pentobarbital sodium 400 mg

(which corresponds to 364.6 mg of pentobarbital)

Excipients:

Qualitative composition of excipent(s) and other constituent(s)	Quantitative composition
Benzyl alcohol (E 1519)	20 mg
Patent Blue V (E 131)	0.01 mg
Ethanol 96%	
Propylene glycol	
Water for injection	

Clear, blue solution.

Target species

Cattle, horses (ponies), pigs, dogs, cats.

Indications for use

Product intended for use in euthanasia of cattle, horses (ponies), pigs, dogs and cats.

Contraindications

Do not use for anaesthesia.

Special warnings

None

Special precautions for safe use in the target species:

Pentobarbital injected intravenously may cause drug induced agitation. To prevent it, administer a proper sedatives before administration of pentobarbital.

Intraperitoneal injection may produce prolonged drug induced agitation; this route of administration may only be used after the animal has been properly sedated.

In order to reduce the risk of agitation, animals should be euthanised in a peaceful environment.

Do not administer the product per os.

Avoid intrasplenic drug administration or injections to organs/tissues with reduced absorption capabilities; this route of administration is only permitted in case of small animals.

Intracardial administration is only possible when the animal has been fully sedated, unconscious or anaesthetized.

Once cardiac and respiratory arrest have been confirmed, monitor the animal for another 10 minutes. In case of finding any signs of life, such as respiration, heartbeat or corneal reflex, it is recommended to re-administer the full or half the recommended product dose.

In case of accidental administration of the product to animals not intended for euthanasia, begin ventilation, administer oxygen and analeptics immediately.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Persons with known hypersensitivity to barbiturates and pregnant women should avoid direct contact with the veterinary medicinal product.

Pentobarbital is a potent hypnotic and sedative, therefore it may be toxic for humans once ingested or absorbed through the skin.

Particular caution should be taken to avoid accidental ingestion or self-injection.

In case of accidental self-injection, swallowing, spilling on skin, contact with eyes, seek medical advice immediately and show the package leaflet or the label to the physician.

Immediate medical advice is particularly important in case of self-injection.

In case of spilling on skin, immediately flush the affected area with plenty of water.

In case of contact with eyes, immediately rinse with plenty of water and seek medical advice.

In case of swallowing, rinse mouth and seek medical advice.

In case of contact with the product, do not drive, as sedation is likely to occur.

While administering the product, use impermeable protective gloves.

To the physician:

Pentobarbital concentration in the product is high enough to produce a serious effect on the central nervous system in an adult after accidental self-injection or swallowing of as much as 1 ml. It was found that a dose of 1 g of pentobarbital sodium (which corresponds to 2.5 ml of the product) may be lethal for humans. In case of poisoning on pentobarbital, extend intensive care in order to sustain blood circulation and respiration.

Other precautions:

Consumption of remains of a euthanised animal by other animals may lead to poisoning, sedation or even death. Barbiturates show high stability even at high temperatures. Due to the risk of secondary poisoning, remains of euthanised animals, even after being heat treated, must not be used for feeding to other animals. They should be disposed of in accordance with the local regulations and in a manner preventing access by other animals.

Pregnancy and lactation:

The product can be used in pregnant and lactating animals. <u>Interaction with other medicinal products and other forms of interaction:</u>

While euthanizing an aggressive animal when intravenous administration is difficult, it is recommended to use premedication with a sedative that is easier to administer (per os, subcutaneously or intramuscularly).

Premedication with sedatives, due to impaired circulation,

may delay the expected effect of pentobarbital. This may not be reflected in clinical signs, as agents used for premedication (opioids, agonists of alpha-2 adrenergic receptors, phenothiazines, etc.) by depressing the central nervous system may enhance the pentobarbital performance.





Morbital Plus



Injection solution intended for cattle, horses, pigs, dogs and cats (pentobarbital sodium 400 mg/ml)

Overdose: Not applicable.

Special restrictions for use and special conditions for use:

None

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

Minor muscle contractions may be observed in the animal after administration of the veterinary medicinal product. When an intravenous injection is not properly administered into a vein or the product is injected to organs with reduced absorption capabilities, death may be delayed. Barbiturates may produce an irritating effect in case of perivascular administration.

Pentobarbital sodium may cause animal agitation. Premedication/sedation significantly reduces the risk of agitation.

At times, after cardiac arrest, agonal respiration may be observed in the animal. At this stage, the animal is dead in clinical terms

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605,

https://smz.ezdrowie.gov.pl

Dosage for each target species, routes and method of administration

Dogs, cats, pigs, piglets – administration of Morbital Plus in ml per 1 kg body weight

	Pentobarbital sodium mg/kg m.c.	Morbital plus in mg/kg m.c.	Route(s) and method of administration
Dogs, cats	100-200 mg	0.25-0.5 ml/kg b.w. b.w.	rapid intravenous or intracardial injection
Pigs	100-200 mg	0.25-0.5 ml/kg b.w. b.w.	rapid intravenous injection
Piglets	100-200 mg	0.25-0.5 ml/kg b.w. b.w.	rapid intravenous or intracardial injection

<u>Cattle, horses, ponies – administration of Morbital Plus in ml/100 kg b.w.</u>

Cattle	50 mg	12.5 ml/100kg b.w.	rapid intravenous injection
Horses,	50 mg	12.5 ml/100kg b.w.	rapid intravenous injection

Intravenous injection should be the preferred method of administration. In necessary, before administration of the veterinary medicinal product, a proper sedative should be used. In case of cattle and horses, premedication is compulsory.

In case intravenous administration is problematic, intracardiac injection may be applied only after prior use of deep sedation or anaesthesia.

In small animals, intraperitoneal administration is allowed, but must be preceded by proper sedation. In pets, pentobarbital should be administered at a fixed pace until loss of consciousness is acknowledged.

In horses and cattle, pentobarbital must be administered as a rapid injection.

Advice on correct administration

Do not administer the product with visible signs of deterioration.

Withdrawal period(s)

Not applicable.

Appropriate actions must be taken to ensure that remains of animals this veterinary medicinal product was administered to, as well as animal-by products from these animals will not enter the food chain and will not be destined for consumption by humans or other animals.

Special storage precautions

Store in the original package.

Store below 25°C.

Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if applicable

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems.

Package size: 100 ml Shelf life: 2 years

To be administered exclusively by a veterinarian. Prescription-only veterinary medicine.

Possession and distribution of the product are regulated by laws concerning narcotic drugs or psychotropic substances.

Marketing authorisation number: 3218/22

SPC: 2022-12-08





Mycosalmovir



Inactivated vaccine against mycoplasmosis, salmonellosis and paramyxovirus infection in pigeons

Active substance and excipient content

1 dose of the vaccine (0.2 ml) contains:

inactivated PMV-1 (La Sota strain) no less than 1 ELISA unit, inactivated *Mycoplasma gallispeticum* cells no less than 1 ELISA unit

inactivated Salmonella cells (serotypes: S. typhi, S. paratyphi A, S. paratyphi C, S. typhimuriumvar. Copenhagen, S. anatum, S. senftenberg) no less than 1 ELISA unit for each serotype.

1 ELISA unit – the quantity of antigen sufficient to obtain seroconversion equal to or higher than 1.8 in a vaccinated pigeon

Adjuvant:

Montanide ISA 763 A VG 0.14 ml

Therapeutic indications

Active immunisation of pigeons in order to reduce mortality and clinical symptoms of salmonellosis, mycoplasmosis and paramyxovirosis in pigeons.

The postvaccinal immunity occurs approx. 21 days after revaccination and remains for approximately 12 months.

Contraindications

Do not use in weak, verminous and sick birds. Do not use in moulting of pigeons.

Adverse reactions

Rarely reported adverse reactions are temporary lack of appetite and apathy occurring within several hours after administration of the preparation and a temporary local reaction in the form of a small tuber.

Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from https://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Amount to be administered per species, method and route of administration

The dose for one pigeon is 0.2 ml of the oil emulsion which should be injected subcutaneously in the middle of the neck. The vaccine is used in pigeons from the age of 3 – 4 weeks. The basic vaccination of young pigeons not immunised against salmonellosis, paramyxovirosis and mycoplasmosis includes two injections at a four-week interval. The vaccination should be planned in such a way that the second administration of the vaccine does not take place later than three weeks before migration. Vaccination of adult pigeons which were immunised with Mycosalmovir several times should be conducted annually 2-3 weeks before mating and exhibitions.

Instructions for use

Sterile needles and syringes ought to be used for vaccinations. Warm containers with the vaccine to room temperature after taking them from a refrigerator and mix the content thoroughly before beginning the procedures.

During the vaccination procedure, mix the content of the container regularly.

Conduct the procedures at an ambient temperature not lower than 0° C.

Once the container is opened, the product cannot be stored and used again.

Withdrawal period

Zero days.

Special precautions for storage

Keep out of the reach and sight of children.

Store in a refrigerator (2-8 $^{\circ}$ C). Do not freeze. Protect from light.

The durability period after the first opening of the immediate container: 10 hours.

Do not use the veterinary medicinal product after the expiry date stated on the label. The expiry date refers to the last day of the given month.

Special warnings

Special precautions to be taken by the person administering veterinary medicinal product to animals:

In the case of accidental self-injection, immediately seek medical advice even if only a small dose of the product has been injected and show the package leaflet to the physician. If the pain remains longer than 12 hours after medical aid is provided, consult the physician again.

Laying period:

The vaccine should not be used during the laying period.

<u>Interactions with other medicinal products or other forms of interactions:</u>

There is no information concerning safety and efficiency of the vaccine used in combination with other medicinal veterinary products. Therefore, the decision to use this vaccine before or after administration of another medicinal veterinary product should be considered individually.

Overdose (symptoms, emergency procedures, antidotes):

After administration of a double dose, no other adverse effects occurred than those specified in the section concerning adverse effects.

Pharmaceutical incompatibilities:

Since no studies of the conformity of this veterinary medicinal product have been conducted, this product must not be combined with other medicinal veterinary products.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Package sizes: 50, 100 doses
Shelf life: 18 months
For animal use only.
Prescription-only – Rp.
To be administered under veterinary supervision.

Marketing authorization: 986/00 SPC: 2015-08-20





the power of a good formula

NeoplasmaVET

Capsules for dogs supporting nutrition during cancer treatment





- trans-resveratrol a natural polyphenol that helps protect cells against carcinogenic factors
- quercetin a natural flavonoid with strong antioxidant properties
- vitamin E and selenium enhance natural immunity by supporting T-lymphocyte activity

Composition

Plant-derived ingredients:

Japanese Knotweed (Polygonum cuspidatum)
Japanese Pagoda Tree (Sophora japonica L.)

Dietary additives:

3a700/Vitamin E - 18,248 mg/kg

3b801/Sodium selenite – 67 mg/kg

Technological additives (emulsifiers):

1c322/Lecithin – 182,482 mg/kg

<u>Technological additives (anti-caking agents):</u>

E 551b/Colloidal Silica – 54,745 mg/kg

Sensory additives (capsule shell components):

E172/Yellow Iron Oxide - 3,026 mg/kg

E132/Indigotine - 1,316 mg/kg

Analytical Constituents

Crude fat 17.84%, Crude ash, 7.72%, Crude protein 1.55% Phosphorus 0.5%, Crude fiber, Sodium <1.0%, Calcium <1.0%

Properties and indications

NeoplasmaVET supplements the diet of dogs with ingredients that strengthen the body and improve the quality of life of sick animals. Japanese Knotweed contains **transresveratrol**, a natural polyphenol that helps protect cells from carcinogenic factors. It positively impacts the circulatory system by improving microcirculation. Japanese Pagoda Tree contains **quercetin**, a powerful natural flavonoid with antioxidant properties, helping protect cells from the harmful effects of oxygen-free radicals. **Selenium** is a component of enzymatic proteins that protect cells from oxidative stress. **Vitamin E** and **selenium** enhance the natural immune response by supporting the activity of T lymphocytes, which

play a crucial role in the immune system's defense mechanisms.

NeoplasmaVET is recommended for dogs:

- Predisposed to cancer
- Diagnosed with cancer
- Undergoing palliative care to improve their quality of life

Dosage

1 capsule per 10 kg of body weight per day. The contents of the capsule should be mixed with food or administered directly into the mouth.

It is recommended to use NeoplasmaVET under the guidance of a veterinarian.

Storage conditions

Store at room temperature in the original packaging. Protect from light and moisture.

Package size:

40 openable capsules (350 mg per capsule)

Shelf life: 2 years

Complementary feed for dogs.

Veterinary identification number: 06148301 Leaflet preparation date: 2024-10-24



support during cancer



NeoplasmaVET amino

Capsules for cats supporting the body during cancer



- trans-resveratrol and quercetin inhibit the development of cancer cells
- quercetin and taurine have strong antioxidant properties
- vitamin E and selenium support T-lymphocyte activity
- **amino acids** and lecithin stimulate the immune system

Composition

Plant-derived ingredients:

Japanese knotweed (Polygonum cuspidatum) Japanese pagoda tree (Sophora japonica L.)

Dietary additives/Vitamins per kg:

3a370/Taurine – 95,837 mg

3a700/Vitamin E - 8,440 mg

Dietary additives/Amino acids per kg:

3c451/L-glutamine - 159,729 mg

3c361/L-arginine - 143,756 mg

Dietary additive/Trace element compound per kg:

3b801/Sodium selenite - 43.8 mg

Technological additive/Emulsifier per kg:

1c322/Lecithin - 63,892 mg

Technological additive/Anti-caking agent per kg:

E 551b/Colloidal silica – 31,946 mg

Capsule shell ingredients:

Porcine-bovine gelatin

Sensory additive per kg:

E172/Red iron oxide - 20,000 mg

Analytical Constituents

Crude protein -61.4%, Crude fat -1.6%, Crude fiber -<0.3%, Crude ash -4.2%, Moisture -5.4%

Properties

Trans-resveratrol and **quercetin** are polyphenols that help protect cells from carcinogenic factors. **Trans-resveratrol** derived from Japanese knotweed supports cardiovascular function by improving microcirculation. **Quercetin** from the Japanese pagoda tree and **taurine** have strong antioxidant properties, protecting the body against the harmful effects of

free radicals. **Vitamin E** and **selenium** enhance natural immunity by supporting T-lymphocyte activity, which plays a key role in the body's immune response. **Amino acids** and **lecithin** stimulate the immune system to combat oncological disease

Indications

- Supportive therapy in oncological disease
- During post-oncological treatment recovery to improve quality of life
- For breeds predisposed to cancer

Dosage and administration

1 capsule once daily. The capsule contents may be mixed with other food.

If the diet consists exclusively of dry food, slightly moisten the kibble to ensure the powder adheres to the food and is fully consumed.

NeoplasmaVET amino should preferably be used after consultation with a veterinarian.

Storage conditions

Store at room temperature in the original packaging. Protect from light and moisture.

Package size:

40 openable capsules (389 mg per capsule)

Shelf life: 2 years

Complementary feed for cats.

Veterinary identification number: 06148301 Leaflet preparation date: 2024-10-24



just a moment to care for your pet's health



Ear care product for dogs and cats





facilitates the penetration of active substances

from medications

soothes and reduces itching

cleans and cares for the ears

Composition

Xylene, glycerin, menthol, thymol, and propylene glycol.

Properties and action

Xylene, due to its cerumenolytic action, ensures excellent solubility of earwax. Glycerin and propylene glycol, with their softening and soothing properties, facilitate the penetration of active substances and provide excellent tolerance of the solution. Glycerin also has strong dissolving properties.

Menthol and thymol combine antiseptic and dehydrating properties (imparting fragrance). The combination of these properties makes OTICLAR an excellent ear care product for dogs and cats.

Indications

OTICLAR can be used for regular ear hygiene in dogs and cats, once or twice a week. In ear diseases, it is typically used for the initial cleaning of the ear canal before applying the appropriate therapeutic agent, as an excessive amount of earwax may reduce the effectiveness of the primary treatment.

Instructions for use

For external use in the ears.

Introduce a few milliliters of the solution into the ear canal and clean, repeating the procedure until the ear is fully cleaned. If earwax production is excessive, the product can be

used once daily for two or three consecutive days without the risk of complications. In dogs (especially those with floppy ears) suffering from chronic otitis externa, daily use of the product can help achieve faster improvement.

Contraindications

Do not use in cases of inner ear infections.

In cases of otitis externa, use the product for initial cleaning before applying the appropriate treatment.

Do not use in animals with skin hypersensitivity to the ingredients (allergy).

Storage conditions

Store at a temperature not exceeding 25°C. Keep out of sight and reach of children.

Package size: 50 ml bottles

Shelf life: 2 years

For animal use only.

Leaflet preparation date: 2013-10-25



Oxytan 200



Injection solution intended for cattle, sheep and pigs (oxytetracycline 200 mg/ml)

Active substance and excipient content

Oxytetracycline – 200 mg/ml (in the form of oxytetracycline dihydrate 216 mg/ml)

Therapeutic indications

The product is intended for use in the treatment of infections induced by microorganisms sensitive to the effect of oxytetracycline, especially in the treatment of:

- atrophic rhinitis induced by Bordetella bronchiseptica, Mannheimia haemolytica and Pasteurella multocida,
- conditions of the umbilicus and joints induced by Arcanobacterium pyogenes, E. coli or Staphylococcus aureus,
- mastitis induced by Corynebacterium pyogenes, E. coli, Staphylococcus aureus, Streptococcus agalactiae or Streptococcus uberis,
- endometritis induced by E. coli or Streptococcus pyogenes,
- pasteurellosis and respiratory infections induced by Mannheimia haemolytica and Pasteurella multocida,
- septicaemia induced by Salmonella dublin and Streptococcus pyogenes,
- Erysipeloid of Rosenbach induced by Erysipelothrix rhisiopathiae.

Oxytan 200 can also be used to eliminate enzootic abortion in sheep.

Contraindications

Do not use in the case of hypersensitivity to tetracyclines or any component of the product.

Do not use in horses, dogs and cats.

Do not use in animals with renal and hepatic disorders.

Adverse reactions

Sometimes, temporary reactions in the form of pain and/or swelling might occur at the injection site, but they subside spontaneously.

Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from https://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Posology for each species, routes and methods of administration

The product should be administered in a single dose, intramuscularly deep into the muscle, in the dose of 20 mg/kg b.w., i.e. 1 ml/10 kg b.w.

The maximum dose administered in one site is as follows:

Cattle: 20 ml Pigs: 10 ml Sheep: 5 ml

Piglets: one day old 0.2 ml

seven days old 0.3 ml 14 days old 0.4 ml 21 days old 0.5 ml

over 21 days old 1.0 ml/10 kg b.w.

Recommendations for proper administration

In order to ensure that administration is appropriate, the bodyweights of the treated animals should be estimated as accurately as possible. General aseptic rules should be observed during the use of the product. The product should not be diluted before use.

Withdrawal period

Cattle

Edible tissues – 31 days

Milk-10 days

Sheep:

Edible tissues - 9 days

Milk-7 days

Pigs:

Edible tissues – 18 days

Special precautions for storage

Keep out of the reach and sight of children.

Store at a temperature below 25oC. Protect from light. Do not freeze.

Use within 28 days after first opening of the immediate packaging.

Do not use the veterinary medicinal product after the expiry date stated on the label and the box.

The durability period after the first opening of the immediate container: 28 days.

Special warnings

Special precautions for use in animals:

Pathogen sensitivity to oxytetracycline might be varied. Therefore, use of the product should be based on tests of drug resistance of microorganisms isolated in the given case. If this is impossible, the treatment should be performed on the basis of available local epidemiological information, including official regulations and guidelines.

Improper use of the product might lead to an increased number of oxytetracycline-resistant bacteria and to reduced efficiency of treatment using other tetracyclines as a result of cross-resistance.

In the case of conditions with concomitant impairment of renal functions, the half-life of oxytetracycline is significantly longer and, in the case of multiple administrations, it may accumulate in the body.

If repeated administration of the drug is required, it should not be injected in the area of the body used for the previous injection.

Special precautions for persons administering the veterinary medicinal product to animals:

People with diagnosed hypersensitivity to tetracyclines should avoid contact with the product. During the use of the veterinary medicinal product, caution should be taken to avoid accidental self-injection and contact with skin and mucosa.

In the case of accidental self-injection, immediately seek medical advice and show the package leaflet or the package to the physician.





Oxytan 200



Injection solution intended for cattle, sheep and pigs (oxytetracycline 200 mg/ml)

If the product comes into contact with an eye, wash the eye with plenty of water and seek medical advice.

If, as a result of the contact with the product, such symptoms as a rash occur, you should seek immediate medical advice and show the package leaflet or the leaflet to the physician. Swelling of the face, lips or eyes as well as breathing difficulties require immediate medical help.

Pregnancy:

Do not use in pregnancy.

Use of oxytetracycline during bone formation might cause their developmental disorders. Administration of oxytetracycline at the end of pregnancy might cause teeth enamel discoloration.

Lactation:

The product can be used in lactation.

<u>Interactions with other medicinal products or other forms of interactions:</u>

Tetracyclines chelate with divalent metal cations. Therefore, combining them with mineral products and infusion fluids is not recommended.

Overdose (symptoms, procedures concerning immediate help and antidotes):

Specific antidote does not exist.

In the case of overdose, discontinue administration of the drug and apply symptomatic treatment.

Pharmaceutical incompatibilities:

Unknown

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Shelf life

Shelf life for a medicinal veterinary product packed for sale: 2 years.

Available containers: 100 ml

Other information

For more information about this veterinary medicinal product, contact the Marketing Authorization Holder.

For animal treatment only.

Subject to medical prescription – prescription drug. To be administered under veterinary supervision.

Marketing authorization number: 2499/15 SPC: 2015-12-01





Oxytocinum Biowet Puławy



Injection solution intended for cattle, horses, pigs, sheep, dogs and cats (okxytocin 10 i.m./ml)

Active substance and excipient content

1 ml contains:

Active substance:

oxytocin 10 IU

Excipient:

chlorobutanol hemihydrate

Therapeutic indications

Stimulation of uterine contractions to induce labour.

Support of involution of the uterus after labour.

Increasing contractility of the myometrium after labour in order to prevent haemorrhage and retained placenta.

Induction of milk letdown in the case of postpartum dysgalactia.

Contraindications

The use of oxytocin is absolutely contraindicated in the following situations:

- obstruction of the reproductive tract (labour with the cervix closed, no full dilation of the cervix, improper position of the foetus/foetuses, etc.),
- occurence of tetanic contractions

Adverse reactions

The effect of high oxytocin doses depends on the functional condition of the uterus and the position of the foetus. Excessive uterine contractions or tetanic contractions induced by oxytocin may lead to exaggerated intensification of labour, metrorrhexis, damage to the foetus or even deaths of unborn foetuses. Intravenous administration of oxytocin for a longer period of time in a large volume of infusion fluid poor in electrolytes may lead to water intoxication of the female. Early symptoms of the intoxication are sadness and depression. Later a coma, convulsions and death of the female may occur. Oxytocin-induced water intoxication requires administration of drugs increasing diuresis.

Failure to observe intervals between successive oxytocin doses (minimum 30 minutes) may lead to excessive uterine contractions.

An allergic reaction may occur in females of all domestic mammals after administration of natural oxytocin instead of the synthetic one.

Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from https://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Amount to be administered per species, method and route of administration

The product should be administered in a single intramuscular or subcutaneous injection in the following doses:

cattle, horses: 3-5 ml (which corresponds to 30-50 IU), pigs, sheeps: 2-3 ml (which corresponds to 20 - 30 IU), 0.5-1.5 ml (which corresponds to 5 – 15 IU), dogs:

0.3-0.5 ml (which corresponds to 3-5 IU). cats:

In justified cases, the product can also be administered intravenously. However, reduction of the dose to approx. 1/4 of the recommended dose for other routes of administration is advised. Administer in an infusion or a slow injection (having diluted it in physiological saline) after the product has been warmed to body temperature.

If necessary, the injection can be repeated, but not sooner than after 30 minutes.

Indications for proper administration

None

Withdrawal period

Edible tissues

Cattle, horses, swine, sheep – zero days.

Milk

Cattle, sheep – zero hours

Dogs, cats – not applicable.

Special precautions for storage

Keep out of the reach and sight of children.

Store at a temperature of $2^{\circ}C - 8^{\circ}C$.

Do not freeze.

Protect from light.

Do not use the veterinary medicinal product after the expiry date stated on the label.

The durability period after the first opening of the immediate container: 28 days.

Special warnings

Special warnings per target species:

Physiological levels of adrenaline significantly reduce the effect of oxytocin on the myometrium and the mammary gland. Therefore, the treated animals should not be distressed in order to achieve complete efficiency.

Special precautions for use in animals:

Metabolic disorders should be eliminated pharmacologically in animals with hypoglycaemia and hypocalcaemia before administration of oxytocin.

Before administration during labour, complete dilation of the cervix must be confirmed.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Caution should be taken to avoid accidental self-injection. In the case of accidental self-injection, immediately seek medical advice and show the package leaflet or the label to the physician. Women, especially those breastfeeding and in advanced pregnancy, should avoid contact with the product since oxytocin may induce contractions of smooth muscles (e.g. uterine muscles).

Pregnancy and lactation:

Oxytocin is used to increase uterine contractions during labour and in lactation in

order to empty the mammary gland of milk or inflammatory secretion.

Oxvtocin is contraindicated in the last stage of pregnancy due to the risk of miscarriage.











Injection solution intended for cattle, horses, pigs, sheep, dogs and cats (0xvtocin 10 i.m./ml)

<u>Interactions with other medicinal products and other forms of interaction:</u>

Interaction between oxytocin and insulin and glucagon leads to an increase in the concentration of glucose.

Overdose (symptoms, procedures concerning immediate help and antidotes):

The result of administration of too high a dose of oxytocin may be a long-lasting uterine contraction in concomitance with hypoxia in foetuses or metrorrhexis. Tachycardia may occur.

The effect of oxytocin is removed by beta-adrenomimetics (e.g. clenbuterol, bamethan) and progesterone.

Pharmaceutical incompatibilities:

Oxytocin displays pharmaceutical incompatibility with the following substances: warfarin sodium, fibrinolysin, epinephrine bitartrate and prochlorperazine edisylate.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Containers: 50 ml, 100 ml Shelf life: 2 years

For animal treatment only.

Subject to medical prescription – prescription drug

Tobe administered under veterinary supervision.

Other information

For more information about this veterinary medicinal product, contact the Marketing Authorization Holder.

Marketing authorization number: 45/94 SPC: 2015-01-21









Inactivated vaccine against pigeon paramyxovirus infection, injectable emulsion

Composition

Each (0.2 ml) dose of the vaccine contains:

Active substance:

Inactivated PMV-1 (La Sota strain) – not less than 1 ELISA unit 1 ELISA unit – amount of antigen enabling seroconversion equal or higher than 1.8 in a vaccinated pigeon

Adjuvant:

Liquid paraffin - 109 mg

White emulsion.

Target species

Pigeons

Indications for use

The vaccine is intended for use in active immunisation of pigeons, to reduce mortality, clinical signs and paramyxovirus-induced lesions.

Onset of immunity: 3 weeks after vaccination.

Duration of immunity: 1 year.

Contraindications

Do not vaccinate pigeons in the moulting period or infested birds

Do not use in pigeons treated with immunosuppressants.

Special warnings

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:

This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Laying birds:

Do not use the vaccine during the laying period.

Interaction with other medicinal products and other forms of interaction:

None found. It is recommended not to administer other vaccines within 7 days before and after administration of the product.

Overdose:

No side effects other than listed in the adverse events section have been observed after administration of a double dose. <u>Major incompatibilities:</u>

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

Target species: pigeons

Rare (1 to 10 animals/10 000 animals treated):	Apathy ¹ Loss of appetite ² Reaction at the injection site ³
Frequency unknown, cannot be determined based on available data:	Hypersensitivity reaction (anaphylaxis) ⁴

occurs within a few hours after product administration

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605,

https://smz.ezdrowie.gov.pl.

Dosage for each target species, route(s) and method(s) of administration

Subcutaneous administration.

1 dose is 0.2 ml of the oil-based emulsion.

The vaccine should be used in young pigeons less than 3 weeks of age, but not later than within 2 weeks before pigeon races or exhibitions.

Adult pigeons should be immunised every 12 months.

The best vaccination time is 2-3 weeks before pigeon pairing. Dose per one pigeon regardless of age is 0.2 ml of the emulsion, to be injected subcutaneously in the middle of the back part of the neck.

Advice on correct administration

Before the vaccination procedure, warm the vial with the vaccine to ambient temperature and mix thoroughly.

Vaccination should be planned so as to use the entire package contents during one day.

Vaccination should be performed at outdoor temperature not lower than 0°C.

Birds should be revaccinated every

Withdrawal period(s)

Zero days.

Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator ($2^{\circ}C - 8^{\circ}C$). Do not freeze. Protect from light.

Do not use this veterinary medicinal





² transient event

³ emerges as a bump spontaneously subsiding after a few days

⁴ if the event occurs, administer adrenalin and anti-histamine drugs immediately





Inactivated vaccine against pigeon paramyxovirus infection, injectable emulsion

product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Use the contents of the immediate package within 10 hours.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Contact details

e-mail: sekretariat@biowet.pl

Marketing authorisation holder and manufacturer responsible for batch release:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel./Fax: + 48 (81) 886 33 53, Tel.: + 48 (81) 888 91 00

<u>Contact details to report suspected adverse events:</u> Biowet Puławy Sp. z o.o. Henryka Arciucha 2

24-100 Puławy Poland

Tel: + 48 (81) 888 91 33, + 48 509 750 444

e-mail: biowet@biowet.pl

Package size: 20 ml bottle containing 100 doses of vaccine

Shelf life: 18 months

For animal use only Prescription-only veterinary medicine To be administered under veterinary supervision

Marketing authorization number: 743/99 SPC: 2025-01-17









Injection solution intended for horses, cattle, pigs, sheep and dogs (sodium sulfadimidine 50 mg, sodium sulfacetamide 40 mg, sodium sulfathiazole 30 mg)

Composition

Each ml contains:

Active substances:

Sulfadimidine sodium – 50 mgSulfacetamide sodium – 40 mg

Sulfathiazole sodium – 30 mg $\,$

Excipient:

chlorocresol – 2 mg Brown solution.

Target species

Horses, cattle, pigs, sheep, dogs.

Indications for use

Horses:

- respiratory infections caused by *Staphylococcus spp., Streptococcus equi, Pasteurella multocida,*
- gastrointestinal infections caused by Salmonella spp.,
- urinary infections caused by Streptococcus spp., Salmonella spp.,
- genital tract infections caused by Streptococcus spp., Escherichia coli, Klebsiella pneumoniae, Salmonella abortus equi,
- soft tissue infections caused by Staphylococcus spp., Streptococcus spp.,

Cattle:

- primary and secondary respiratory infections caused by Haemophilus somnus, Mannheimia haemolitica, Pasteurella multocida.
- enzootic pneumonia in calves (BRD) caused by *Mannheimia haemolitica*, *Pasteurella multocida*,
- colibacillosis in calves caused by Escherichia coli,
- calf diphtheria caused by sensitive Fusobacterium necrophorum,
- mastitis caused by Staphylococcus spp., Streptococcus spp., Escherichia coli.

Sheep:

- respiratory infections caused by Haemophilus somnus, Mannheimia haemolitica, Pasteurella multocida,
- enteritis caused by Escherichia coli,

Pigs:

- respiratory infections, including atrophic rhinitis in pigs caused by Streptococcus suis, Actinobacillus pleuropneumoniae, Actinobacillus suis, Bordatella bronchiseptica, Haemophilus parasuis, Pasteurella multocida,
- gastrointestinal infections caused by *Escherichia coli, Salmonella choleraesuis,*
- genitourinary infections: cystitis, urinary tract infection, MMA syndrome, postpartum infections caused by *Staphylococcus spp., Streptococcus spp., Escherichia coli, Klebsiella spp.,*

Dogs:

- laryngitis, bronchitis and pneumonia caused by *Staphylococcus* spp., *Streptococcus* spp., *Bordatella bronchiseptica*, *Klebsiella* spp.,
- enteritis caused by Escherichia coli, Salmonella spp.,
- soft tissue infections caused by Staphylococcus spp., Streptococcus spp., Proteus spp., Nocardia spp.

Contraindications

Do not use in case of hypersensitivity to the active substances or to any of the excipients.

Do not use in animals with renal and hepatic failure, haematopoietic disorders, in dehydrated animals or in animals

not taking water.

Do not use in pregnant and very young animals.

Special warnings

Special warnings:

Administration of excessively low doses of the product or excessively short therapy leads to development of microbial resistance to sulphonamides. For this reason, results of antimicrobial susceptibility testing must confirm the need of sulphonamide use.

During treatment, animals should be given plenty of water or provided with free access to water to prevent the development of crystalluria.

Sulphonamides are less efficient in purulent drainage and necrotic tissues.

Special precautions for safe use in the target species:

The veterinary medicinal product should be used based on results of microbial resistance for bacteria isolated from diseased animals. If this is impossible, administered treatment should be based on the local epidemiological information concerning susceptibility of isolated bacteria.

After administration of sulphonamides, animals may have difficulty passing urine, cloudy urine or haematuria, therefore they should be closely monitored during treatment.

Animals with hypersensitivity to sulphonamides may develop haematuria or apathy. In that event, discontinue administration of the product.

Dogs are particularly sensitive to sulphonamide action, large breed dogs in particular, in which administration of the product may elicit hypersensitivity reactions.

In case of intramuscular or subcutaneous administration, the product should be injected in a number of different sites.

In case of intravenous injection, the product should be warmed to body temperature and injected slowly.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy:

Do not use during pregnancy.

<u>Lactation</u>

The product can be used during the lactation period.

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with methenamine and local anaesthetics belonging to the group of esters of para aminobenzoic acid.

Do not use simultaneously with acetylsalicylic acid.

Sulphonamides may transport drugs strongly binding with proteins, such as methotrexate, warfarin, phenylbutazone, thiazide diuretics, salicylates or probenecid. Therefore, concentrations of these drugs must be monitored. Using the product simultaneously with myelosuppressive drugs aggravates





Polisulfamid[®]



Injection solution intended for horses, cattle, pigs, sheep and dogs (sodium sulfadimidine 50 mg, sodium sulfacetamide 40 mg, sodium sulfathiazole 30 mg)

leucopoenia and thrombocytopenia. Using the product simultaneously with hepatotoxic drugs enhances their negative effect on the liver. Since the bacteriostatic effect of sulphonamides may interfere with the bactericidal effect of penicillin, it is not recommended to use them simultaneously.

Overdose:

Overdose leads to circulatory failure and induces signs of the central nervous system, such as ataxia, significant apathy. Coma may occur in instances of acute poisoning. In cattle, acute poisoning may promote signs of anaphylaxis, manifested in muscle tremor, muscle paralysis and visual impairment.

Overdosing sulphonamides may result in bone marrow damage, aplastic anaemia, granulocytopenia and thrombocytopenia. It may cause hepatitis, icterus, neuritis, degeneration of the spinal cord and peripheral nerves, stomatitis and keratitis.

Overdose in dogs may result in thymic hyperplasia or hypothyroidism.

In case of overdose, administer symptomatic treatment.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

Target species: Horses, cattle, pigs, sheep, dogs.

Frequency unknown (cannot be determined on the basis of available data):

- apathy¹, fever¹
- collapse³, anaphylaxis¹
- difficulty passing urine, cloudy urine, hematuria¹, crystalluria, renal tubular obstruction
- swelling at the injection site², skin lesions¹, hives (urticaria)¹
- ataxia³, muscle weakness³
- arthritis¹
- haemolytic anemia¹, agranulocytosis¹
- blindness³
- gastrointestinal tract disorders⁴
- ¹ May occur in animals with hypersensitivity to sulphonamides.
- ² May occur after intramuscular or subcutaneous administration.
- ³ May occur in case of rapid intravenous injection.
- ⁴ May occur as a result of bacteriostatic action of sulphonamides on gastrointestinal microbiota. This particularly applies to ruminants in which as a result of bacteriostasis of forestomach microbiota, synthesis of vitamin B may be impaired.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warszawa, Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605,

https://smz.ezdrowie.gov.pl.

Dosage for each target species, route(s) and method(s) of administration

The veterinary medicinal product should be administered intravenously, intramuscularly, intraperitoneally and subcutaneously.

Dosage: horses, cattle, pigs, sheep, dogs

Therapeutic dose for specific active substance:

sulfadimidine sodium 20-50 mg/kg b.w.

sulfacetamide sodium 16-40 mg/kg b.w.

sulfathiazole sodium 12-30 mg/kg b.w.

i.e. 48-120 mg of total sulphonamides / kg b.w.

Dosage in ml/kg b.w.:

horses, cattle, pigs, sheep, dogs: 0.4-1.0 ml of the product/kg b.w.

The initial dose should be administered intravenously, which allows to develop high product concentration in the blood.

On consecutive days of treatment, use 2/3 to 1/2 of the initial dose.

Duration of therapy, with efficacy of the veterinary medicinal product confirmed by antimicrobial susceptibility testing, is 5 to 7 days.

Rapid intravenous injection causes toxic effect, producing clinical signs such as muscle weakness, ataxia, blindness and collapse.

Advice on correct administration

During treatment, animals should be given plenty of water or provided with free access to water to prevent the development of crystalluria.

The veterinary medicinal product administered intramuscularly or subcutaneously should be injected at different sites, whereas in case of intravenous injection, the product should be warmed to body temperature.

When administered intravenously, inject the product slowly.

Withdrawal period(s)

<u>Cattle</u>

Meat and offal – 10 days

Milk – 5 days

Sheep:

Meat and offal – 10 days

Do not use in sheep from which milk is intended for human consumption. \\

Pias:

Meat and offal – 10 days

Dogs: not applicable

Do not use in horses from which meat and offal are intended for human consumption.

Horses treated at any time with the veterinary medicinal product must not be intended for slaughter for human consumption.

For use only in horses with signed declaration "not intended for slaughter for human consumption under applicable laws" in the horse passport.

Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2°C-8°C).

Protect from light. Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is









Injection solution intended for horses, cattle, pigs, sheep and dogs (sodium sulfadimidine 50 mg, sodium sulfacetamide 40 mg, sodium sulfathiazole 30 mg)

stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate package: 28 days.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Detailed information on this veterinary medicinal product is available in the Union Product Database

(https://medicines.health.europa.eu/veterinary).

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2

24-100 Puławy Poland

Tel./Fax: + 48 (81) 886 33 53, Tel.: + 48 (81) 888 91 00

e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:

Biowet Puławy Sp. z o.o. Henryka Arciucha 2 24-100 Puławy

Poland

Tel: + 48 (81) 888 91 33, + 48 509 750 444 e-mail: biowet@biowet.pl

Package size: 250 ml

Shelf life: 3 years

For animal use only Prescription-only veterinary medicine To be administered exclusively by a veterinarian

Marketing authorisation number: 789/99 SPC: 2024-09-26





don't waste time on diarrhea

Rehydrat

Electrolyte preparation for calves, lambs, kids, piglets, and foals

(glucose, sodium chloride, sodium bicarbonate, potassium chloride)





- replenishes electrolytes and provides energy
- supports acid-base balance
- helps counteract the negative effects of diarrhea
- comes in a new doypack with a zip-lock for easy resealing and multiple use

Composition:

glucose, sodium chloride, sodium bicarbonate, potassium chloride

Dietary additive:

3b604/Zinc - 570 mg/kg

Analytical constituents:

Chlorides - 96,200 mg/kg

Sodium – 70,000 mg/kg Potassium – 26,700 mg/kg

One sachet (280 g) contains:

Glucose monohydrate – 208.1 g

Sodium bicarbonate - 23.7 g

Rehydrat®

- Replenishes electrolytes
- Supports acid-base balance
- Counteracts the adverse effects of diarrhea
- Provides energy

Properties and indications

Rehydrat restores and maintains the proper balance of water and electrolytes. Glucose facilitates water absorption, serves as a readily available source of energy, and enhances the palatability of the product. Bicarbonate ions act as a blood buffer system, helping to prevent metabolic acidosis. Zinc plays a role in intestinal mucosal repair, alleviating symptoms associated with diarrhea.

Rehydrat is recommended for use in cases of dehydration and electrolyte loss caused by:

- Gastrointestinal disorders accompanied by diarrhea
- Increased physical exertion
- High ambient temperatures

Dosage and administration

Preparation of solution:

Dissolve one sachet (280 g) in 10 liters of water.

Administer 0.5 - 1.0 liter per 10 kg of body weight per day, divided into 2 - 5 portions.

Recommended duration of use: 1 to 7 days (1 to 3 days if used as the sole source of nutrition).

Animals must have access to fresh water at all times.

Rehydrat is best used after consultation with a veterinarian.

Storage conditions

Store at room temperature in the original packaging. Protect from light and moisture.

Net weight: 280 g Shelf life: 18 months

For animal use only

Dietetic feed mixture for calves, lambs, kids, piglets and foals supporting water-electrolyte balance

Veterinary identification number: α PL0614003p Leaflet preparation date: 2022-09-14



professional protection against dehydration



Rehydrat C

Electrolyte supplement for calves, lambs, kids and foals

(glucose, psyllium husk, sodium bicarbonate, sodium chloride, potassium chloride, magnesium oxide)



- ensures proper hydration
- improves intestinal peristalsis
- stimulates regeneration and growth of intestinal cells
- regulates gut flora
- replenishes electrolytes

Composition per 100 g

Glucose (carbohydrate source) – 40.0 g Psyllium seeds (*Plantago ovata*) – 27.0 g

Dried brewer's yeast - 8.0 g

Wheat starch -7.3 g

Sodium bicarbonate - 7.0 g

Sodium chloride – 5.0 g

Potassium chloride – 3.5 g

Magnesium oxide – 1.0 g

Additives per 100 g

Amino acids:

3c451 L-glutamine -0.2 g (2,000 mg/kg)

Vitamins:

 $3a315\,Vitamin\,PP\,(nicotinamide) - 0.8\,g\,(8,000\,mg/kg)\\ 3a700ii\,Vitamin\,E\,(alpha-tocopherol\,acetate) - 0.2\,g$

(2,000 mg/kg)

Analytical Composition

Sodium - 4.0%, potassium - 1.8%, chlorides - 8.5%, magnesium - 0.53%, crude protein - 4.76%, crude fiber - 0.3%, crude fat - <1%, crude ash - 15.1%.

Indications and properties

Used in cases of water-electrolyte imbalance to support physiological digestive functions. Recommended for dehydration and digestive disturbances accompanied by diarrhea. The fiber in psyllium seed husks absorbs water, forming a gel that protects the intestinal mucosa. Glutamine promotes the regeneration of intestinal cells.

Administration

It is recommended to consult a veterinarian before use.

Preparation of solution:

Calves and foals:

Mix 100 g (1 sachet) with 2 liters of water or milk at a temperature of 40° C.

Lambs and kids:

Mix 25 g (1/4 sachet) with 0.5 liters of water or milk at a temperature of 40°C .

Prepare and administer within a maximum of 20 minutes before the solution turns into a gel.

The solution is recommended to be administered every 12 hours:

- -For 1 to 7 days
- For 1 to 3 days if it is the only source of nutrition
 Animals must have access to fresh water at all times.

Storage

Store in a dry, dark place at room temperature in its original packaging.

Packaging

Carton containing 10 sachets x 100 g

Shelf life: 2 years

Dietetic feed mixture intended for calves, lambs, kids, and foals

Veterinary Identification Number: αPL0614003p Leaflet preparation date: 2024-11-27







Inactivated vaccine against salmonellosis and paramyxovirus infection in pigeons

Composition

Each (0.2 ml) dose of the vaccine contains:

Active substances:

inactivated PMV-1 virus (*La Sota* strain) not less than 1 ELISA unit.

inactivated cells of *Salmonella* (serotypes: *S. typhi, S. paratyphi A, S. paratyphi C, S. typhimuriumvar. Copenhagen, S. anatum, S. senftenberg*) not less than 1 ELISA unit for each serotype.

1 ELISA unit – amount of antigen enabling seroconversion equal or higher than 1.8 in a vaccinated pigeon

Adjuvant:

Montanide ISA 763 A VG 0.14 ml White emulsion.

Target species

Pigeons

Indications for use

Active immunisation of pigeons to reduce mortality and clinical signs of salmonellosis and pigeon paramyxovirus.

Onset of immunity: approx. 21 days after revaccination.

Duration of immunity: approx. 12 months.

Contraindications

Do not use in weak, infested and diseased birds.

Do not use in the moulting period.

Special warnings

Special warnings:

Vaccinate healthy animals only.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:

This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this veterinary medicinal product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Laying birds:

Do not use the vaccine during the laying period.

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product, therefore it is not recommended to administer other vaccines within 14 days before and after vaccination using this product.

Overdose:

No side effects other than listed in the adverse events section have been observed after administration of a double dose. Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

Target species: pigeons

Rare (1 to 10 animals/10 000 animals treated):

Apathy¹
Loss of appetite²
Reaction at the injection site³

occurs within a few hours after product administration

³ reaction is transient and it takes the form of a small bump

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605,

https://smz.ezdrowie.gov.pl.

Dosage for each target species, route(s) and method(s) of administration

Subcutaneous injection.

Dose for one pigeon is 0.2 ml of the oil-based emulsion to be injected subcutaneously in the middle of the neck.

The basic vaccination scheme for young pigeons unvaccinated against salmonellosis and PMV includes two injections at a 4-week interval. The first injection should be administered in pigeons 3 to 4 weeks of age, whereas the second not later than within 3 weeks before pigeon races.

Adult pigeons revaccinated many times with Salmovir should be administered a single injection annually, 2 to 3 weeks before pairing or exhibitions.

Advice on correct administration

Use sterile needs and syringes.

Once removed from the refrigerator, warm vaccine packages in ambient temperature and mix thoroughly before commencing the procedure.

During vaccination, mix package content from time to time.

Vaccination should be performed at outdoor temperature not lower than 0°C.

Once opened, do not store and reuse the package.





² transient event





Inactivated vaccine against salmonellosis and paramyxovirus infection in pigeons

Withdrawal period(s)

Zero davs.

Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C). Do not freeze. Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: use immediately.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Detailed information on this veterinary medicinal product is available in the Union Product Database

(https://medicines.health.europa.eu/veterinary).

Contact details

<u>Marketing authorisation holder and manufacturer</u> responsible for batch release:

Biowet Puławy Sp. z o.o.

Henryka Arciucha 2 24-100 Puławy

Poland

Tel./Fax: +48 (81) 886 33 53, Tel.: +48 (81) 888 91 00

e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:

Biowet Puławy Sp. z o.o. Henryka Arciucha 2

24-100 Puławy

Poland

Tel: +48 (81) 888 91 33, +48 509 750 444

e-mail: biowet@biowet.pl

Shelf life: 18 months

Shelf life after first opening of the immediate packaging:

use immediately

Package sizes: 20 doses, 50 doses, 100 doses

For animal use only

Prescription-only veterinary medicine
To be administered under veterinary supervision

Marketing authorization number: 202/95 SPC 2025-01-17









Injection solution intended for cattle, horses, dogs and cats (xylazine 20 mg/ml)

Active substance and excipient content

Xylazine (in the form of hydrochloride) 20 mg/ml

Therapeutic indications

Sedazin is used in cattle, horses, dogs and cats for sedation, reduction of pain, myorelaxation and as a premedication agent. Administration of xylazine facilitates examination of irritable animals, application of drugs and facilitates conduction of short surgical procedures.

Contraindications

Do not use in the case of ventricular arrhythmia, hypotension and in a shock

Do not use in the case of respiratory diseases.

Do not use in advanced pregnancy (risk of miscarriage), except for the labour.

Do not use in the case of diabetes (xylazine reduces the level of insulin).

Do not use in the case of alimentary obstruction in dogs and cats

Adverse reactions

Respiratory weakness with concomitant acidosis, bradycardia, hypotension, frequent urination. Ataxia in large animals, profuse perspiration in horses. Ruminants may experience ruminal atony and flatulence, salivation and diarrhoea.

In cats, less frequently in dogs, vomiting occurs within 3-5 minutes after administration. Sometimes diarrhoea occurs in dogs and cats.

Local reactions may occur after intramuscular or subcutaneous administration, but they normally subside after 48 hours

Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from https://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Amount to be administered per species, method and route of administration

Routes of administration: intramuscular, intravenous and subcutaneous administration.

Sabedtaries as tarrimistration.		
Cattle:	intramuscularly 0.25-1.5 ml/100 kg b.w. (i.e. 5-30 mg xylazine/100 kg b.w.) intravenously 0.08 – 0.5 ml/100 kg b.w. (i.e. 1.6-10 mg xylazine/100 kg b.w.)	
Horses:	intramuscularly 7.5-15 ml/100 kg b.w. (i.e. 150-300 mg xylazine/100 kg b.w.) intravenously 3-5 ml/100 kg b.w. (i.e. 60-100 mg xylazine/100 kg b.w.)	
Dogs	intramuscularly, subcutaneously or intravenously 0.15 ml/kg b.w. (i.e. 3 mg xylazine/kg b.w.)	
Cats:	intramuscularly or subcutaneously 0.15 ml/kg b.w. (i.e. 3 mg/kg b.w.)	

In the case of intravenous administration, the preparation should be warmed to body temperature and injected slowly. In order to determine appropriate dosage, the animal's body weight should be measured as accurately as possible.

In the case of a cardiac disorder, the product should be administered in combination with atropine.

The effect of xylazine begins within 5-10 minutes after intramuscular administration and 3-5 minutes after intravenous administration. Its analgesic effect remains for 10-15 minutes and the sedative effect for 0.5-4 hours, depending on the animal species. The effect after intramuscular administration lasts longer.

Instructions for use

None

Withdrawal period

Cattle and horses:

edible tissues - zero days,

milk – zero days.

Dogs and cats - not applicable.

Special warnings and precautions

Special precautions for use in animals:

Horses:

- Xylazine hinders physiological intestinal peristalsis.
 Therefore, it should only be used in horses in colics resistant to analgesics. Do not use in horses with impaired motility of the caecum,
- · Use carefully in horses susceptible to laminitis,
- In horses with respiratory disorders or respiratory diseases, life-threatening breathlessness might develop,
- The lowest recommended doses should be used.

Cats and dogs:

- Xylazine inhibits regular intestinal motility, which is conducive to gas accumulation in the gastrointestinal tract of the animals. Therefore, the use of xylazine is not recommended before an x-ray examination of the stomach and the foregut because the accumulated gas hampers proper interpretation of the examination results,
- In brachycephalic dog breeds with symptoms of impaired respiratory function or respiratory diseases, lifethreatening breathlessness might develop.

Cattle:

- Under the influence of xylazine, motility of the forestomachs decreases, which may lead to flatulence. Therefore, it is recommended that the animals should not be fed or watered for several hours before administration of xylazine,
- Xylazine weakens reflexes of belching, couching and swallowing. Therefore, cattle must be observed carefully while they are regaining consciousness and must remain in a sternal position,
- In cattle, administration of low and medium doses is recommended.









Injection solution intended for cattle, horses, dogs and cats (xylazine 20 mg/ml)

Avoid administering too high doses of the drug. Adjust dosage considering individual sensitivity of each animal.

Exercise particular caution when using the drug in convulsions, acute renal or hepatic insufficiency and in dehydrated animals.

In order to prevent choking on saliva or vomit, the animal's head should be positioned lower than the rest of the body.

Old and fatigued animals may be more sensitive to the effect of xylazine whereas agitated animals may require higher doses.

During the use of the product, peace should be provided for patients because external stimuli may deteriorate reaction to the product.

Xylazine may impair thermoregulation. If ambient temperature differs from room temperature, cooling or warming the patient is recommended during the use of the product.

In the case of painful procedures, xylazine should be used in combination with local or general anaesthesia.

Treated animals should be monitored until the effects of the product subside completely. During this time, they should be kept in a separate room in order to avoid injuries from other animals.

Drugs with a central neurodepressive effect (anaesthetics, analgesics) boost the effect of xylazine. Intensification of the cardiodepressive effect, weakening of respiratory action and hypotensive effect occurs. Therefore, the combination of xylazine and opioids is used with great caution.

Xylazine should not be combined with thiobarbiturates and halothane due to the consequent intensification of cardiac arrhythmia.

Due to the risk of ventricular arrhythmia, xylazine should not be combined with adrenaline and other drugs stimulating the sympathetic nervous system or used immediately after their administration.

Do not use xylazine in advanced pregnancy because it may lead to miscarriage.

In overdose, adverse effects are intensified: there is a risk of respiratory arrest and collapse; convulsive seizures may occur. Partial elimination of the effect of xylazine may be obtained by administration of central antagonists of $\alpha 2\text{-}adrenergic$ receptors: yohimbine in the dose of 0.1 – 0.2 mg/kg b.w. intravenously or tolazoline in the dose of 0.5 – 1.0 mg/kg b.w. intravenously.

Since no studies of the conformity of this veterinary medicinal product have been conducted, this product must not be combined with other medicinal veterinary products.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

If the product is accidentally swallowed or self-injected, immediately seek medical advice and show the package leaflet to the physician, but do not drive due to the possibility of sedation and changes in the arterial blood pressure.

Avoid contact with skin, eyes and mucosa.

In the case of contact of the product with bare skin, wash the skin with plenty of water immediately.

Remove contaminated clothing being in direct contact with the skin

If the product has accidental contact with an eye, wash the eye with plenty of water. In the case of any symptoms, you should contact a physician.

If a pregnant woman administers the medicinal product, she should take special precautions to prevent self-injection due to the possibility of the occurrence of uterine contractions and reduced foetal arterial blood pressure after accidental general exposure.

Indications for physicians

Xylazine is an agonist of alpha-2-adrenergic receptors. Its absorption may induce dose-dependent clinical symptoms such as: sedation, respiratory depression, bradycardia, hypotension, dryness in the oral cavity and hypoglycaemia. Ventricular arrhythmia was also reported. Respiratory and hemodynamic disorders should be treated symptomatically.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Package sizes: 20 ml and 50 ml

Shelf life: 2 years

For animal treatment only.
Subject to medical prescription – prescription drug
Tobe administered under veterinary supervision.

Name and address of the manufacturer responsible for batch release:

Biowet Puławy Sp. z o.o.

ul. H. Arciucha 2, 24-100 Puławy

Tel/fax: 81 886 33 53; e-mail: sekretariat@biowet.pl

Marketing authorization number: 219/96 SPC: 2013-01-09





Streptovac



Inactivated vaccine against streptococcosis in pigs Injectable emulsion

Composition

Inactivated Streptococcus suis antigens:

serotype 2, concentration before inactivation min. 8.5×108 CFU/dose

serotype 1/2, concentration before inactivation min. 8.5×108 CFU/dose.

Excipients:

Aluminium hydroxide gel

Water oil emulsion

Target species

Pigs

Indications for use

Passive immunisation of piglets via active immunisation of pregnant sows, and active immunisation of piglets, to reduce mortality, clinical signs and (or) pathogenic lesions caused by Streptococcus suis.

Onset of immunity: 2 weeks after vaccination.

Duration of immunity: has not been established.

Strength of immunity is to a large extent determined by proper nutrition and hygienic conditions.

Contraindications

Do not use in diseased animals.

Special warnings

Special precautions for safe use in the target species:

None

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

Overdose:

No adverse events have been observed after administration of a double dose.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

Target species: pigs

Frequency unknown, cannot be	Fever ¹
determined based on available data:	Inflammatory reaction ²

¹ Core body temperature rises by 2°C within a few hours after product administration. Body temperature gets back to normal without administration of treatment.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49-21-687. Fax: +48 22 49-21-605.

https://smz.ezdrowie.gov.pl.

Dosage for each target species, route(s) and method(s) of administration

The product should be administered as two 2 ml doses at the time interval of 2-3 weeks.

Piglets should be vaccinated immediately before weaning and 2-3 weeks later, using a dose of 2 ml injected intramuscularly in the neck area.

Pregnant sows should be immunised between 5 and 2 weeks before parturition.

Advice on correct administration

Before the start of vaccination, transfer the product to room temperature and thoroughly mix the bottle contents immediately before injection.

Use sterile needles and syringes. During vaccination, it is recommendable to mix the package content from time to time.

Vaccination should be planned so as to use the entire package contents during one day.

Withdrawal period(s)

Zero days.

Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C). Protect from light. Do not freeze

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging is 1 day.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.





² Occurs at the injection site, subsides spontaneously.

Streptovac



Inactivated vaccine against streptococcosis in pigs Injectable emulsion

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Contct details

<u>Marketing authorisation holder and manufacturer</u> responsible for batch release:

Biowet Puławy Sp. z o.o. Henryka Arciucha 2 24-100 Puławy Poland

Tel./Fax: + 48 (81) 886 33 53, Tel.: + 48 (81) 888 91 00

e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:

Biowet Puławy Sp. z o.o. Henryka Arciucha 2 24-100 Puławy Poland

Tel: + 48 (81) 888 91 33, + 48 509 750 444

e-mail: biowet@biowet.pl

Package size: 100 ml Shelf life: 1 year

For animal use only
Prescription-only veterinary medicine
To be administered under veterinary supervision

Marketing authorization: 1709/06

SPC: 2025-02-10









Injection solution intended for cattle and pigs (iron (III) as a dextran complex 100 mg/ml)

Composition

1 ml contains:

Active substance:

Iron (III) in the form of a complex with dextran 100 mg

Excipients:

Phenol 5 mg

Therapeutic indications

Prophylactic and therapeutic use in anaemia resulting from iron deficiency. Suiferrin compensates the shortage of iron in the body, stimulates the haematopoietic system for synthesis of haemoglobin and increases the number of erythrocytes.

Contraindications

Hepatic disorders and renal insufficiency.

Hypersensitivity to iron dextran.

Anaemias not resulting from iron deficiency.

Adverse reactions

In rare cases iron dextran induces symptoms of anaphylactic shock in piglets, and in extreme cases – deaths. The causes might be genetic factors, lack of vitamin E or selenium. Irritation, swelling and brown discoloration of adjacent tissues might occur at the injection site. In the case of serious vitamin E and/or selenium deficiencies in the diet of sows, hypersensitivity to iron manifesting itself with nausea, vomiting and sudden death approximately an hour after administration of products containing iron compounds may occur.

Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from https://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Amount to be administered per species, method and route of administration

Use intramuscularly or subcutaneously.

Piglets, weaners: 2 ml per animal.

Calves: 4-8 ml per animal.

$Indications \, for \, proper \, administration \,$

None

Withdrawal period

Edible tissues: zero days.

Special precautions for storage

Keep out of the reach and sight of children.

Do not store at a temperature over 25°C. Store in the original container in order to protect from light. Do not freeze.

The durability period after the first opening of the immediate container: 28 days

Do not use the veterinary medicinal product after the expiry date stated on the label.

Special warnings

Special precautions for use in animals:

Iron dextran may cause an anaphylactic shock in weaners. The causes might be genetic factors, vitamin E or selenium deficiency. If vitamin E and/or selenium deficiencies are suspected, product containing iron compounds should not be used.

The product must only be administered via recommended routes. Intravenous administration may lead to acute poisoning mainly manifesting itself with an anaphylactic shock. Sudden deaths of animals without prodromal symptoms may occur or symptoms from the nervous system may occur: abnormal balance, progressing depression leading to a coma. After oral administration, bloody vomiting, diarrhoea or constipation may occur.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Caution should be taken to avoid accidental self-injection. In the case of accidental self-injection, immediately seek medical advice and show the package leaflet or the label to the physician.

Pregnancy:

Not applicable.

Lactation:

Not applicable.

Interactions with other medicinal products or other types of interactions:

The product should not be combined with oral iron products. Combining the product with tetracyclines and chelating compounds is not recommended because iron ions may form poorly soluble complexes with them which prevent absorption.

Overdose (symptoms, emergency procedures, antidotes):

In overdose, the following disorders of the gastrointestinal tract might occur: bloody vomiting, diarrhoea or constipation. Iron excess may induce a shock, cardiac disorders leading to collapse, breathlessness and renal insufficiency manifesting itself with oliquria or anuria.

Symptoms of chronic iron poisoning result from hepatic disorders caused by accumulation of iron in hepatocytes and Kupffer cells.

Pharmaceutical incompatibilities:

Since no studies of the conformity of this veterinary medicinal product have been conducted, this product must not be combined with other medicinal veterinary products.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Package sizes: 100 ml and 250 ml

Shelf life: 3 years

For animal treatment only.
Subject to medical
prescription.
To be administered

under veterinary supervision.

Marketing authorization number: 2087/11 SPC: 2017-03-23









Injection solution intended for cattle, horses and pigs (sulfadoxine 200 mg/ml, trimethoprim 40 mg/ml)

Composition

Active substances:

Sulfadoxine 200 mg/ml Trimethoprim 40 mg/ml Clear, yellow brown solution.

Target species

Cattle, horses, pigs.

Indications for use

Cattle:

Bacterial pneumonia in calves caused by *Pasteurella* multocida, Mannheimia haemolitica, Corynebacterium pyogenes, Staphylococcus spp., Streptococcus spp.

Bacterial gastroenteritis in calves caused by Salmonella spp., Proteus spp.

Colibacillosis in calves caused by Escherichia coli.

Metritis in cows caused by Staphylococcus spp., Streptococcus spp., Escherichia coli, Haemophilus somnus, Corynebacterium pyogenes, Pseudomonas spp.

Listeriosis caused by Listeria monocytogenes.

Pododermatitis caused by Fusobacterium necrophorum, Bacteroides melaninogenicus and Actinomyces pyogenes.

Horses:

Respiratory infections caused by Staphylococcus spp., Streptococcus spp., Actinobacillus equi, Rhodococcus equi, Pasteurella spp.

Gastrointestinal infections caused by *Rhodococcus equi*, *Actinobacillus equi*, *Salmonella spp*.

Pigs:

Bacterial respiratory tract infections caused by *Streptococcus* suis, *Actinobacillus pleuropneumoniae*, *Actinobacillus suis*, *Bordatella bronchiseptica*, *Haemophilus parasuis*, *Pasteurella multocida*.

Bacterial joint inflammation caused by Arcanobacterium pyogenes, Escherichia coli, Staphylococcus spp., Streptococcus spp.

Colibacillosis in piglets caused by Escherichia coli.

Bacterial gastroenteritis in piglets caused by Salmonella choleraesuis.

Metritis in sows, MMA syndrome caused by Staphylococcus spp., Streptococcus spp., Escherichia coli, Klebsiella spp.

Atrophic rhinitis caused by Bordatella bronchiseptica, Mannheimia haemolytica and Pasteurella multocida.

Contraindications

Do not use in cases of hypersensitivity to the active substance-(s) or to any of the excipients.

Do not use in animals with hepatic and/or renal failure.

Do not use in pregnant animals.

Do not use in animals with blood dyscrasia.

Do not use in dehydrated animals.

Special warnings

Special warnings:

In horses treated with detomidine, administration of the drug may cause severe arrhythmia.

Special precautions for safe use in the target species:

Large doses of the product should be administered intravenously.

In case of intravenous administration, inject the product slowly.

The maximum dose injected intramuscularly or subcutane-

ously should not exceed 20 ml per one site.

The product should be used based on susceptibility test results and local regulations governing the use of sulphonamides

Underdosing or too short duration of treatment may promote the development of drug resistance.

Sulphonamides combined with trimethoprim, especially after prolonged treatment, might cause folate deficiency and deficiency in vitamins produced by gut microbiota.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The product should be administered slowly to avoid accidental self-injection. Wash hands after usage

In case of contact with eyes or skin, immediately flush the affected site with plenty of water.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

People with known hypersensitivity to sulfadoxine or trimethoprim should avoid contact with the veterinary medicinal product, or administer the product with caution. The product should not be administered by pregnant women.

Special precautions for the protection of the environment:

Not applicable.

Pregnancy and lactation:

Do not use during pregnancy.

The product can be used during the lactation period.

<u>Interaction with other medicinal products and other forms of interaction:</u>

The product should not be administered simultaneously with detomidine.

Sulphonamides may compete for blood protein-binding sites with other drugs, such as methotrexate, phenylbutazone, thiazide diuretics, salicylates, probenecid, and phenytoin. Urinary acidifying agents, such as ascorbic acid and ammonium chloride, are likely to increase the risk of precipitation of sulphonamides in the urinary system.

Trimethoprim might increase the efficacy of antithrombotic agents, such as warfarin, by inhibiting its metabolism.

Overdose:

Overdosing the product in newborn animals and individuals with impaired liver and/or kidney functions may result in the accumulation of the drug and its metabolites.

Major incompatibilities:

None known.

Dosage for each target species, routes and method of administration

Horses, cattle, pigs: 13.33 mg of the product/kg body weight, which corresponds to 1 ml of the product/15 kg body weight injected intravenously, intramuscularly or subcutaneously, once daily for 4 to 6 days.

Advice on correct administration

In case of intravenous injection, administer the product very slowly, at the same controlling the animal's respiration and heart rate, as well as the colour of the conjunctiva.









Injection solution intended for cattle, horses and pigs (sulfadoxine 200 mg/ml, trimethoprim 40 mg/ml)

Adverse events

Frequency unknown, cannot be determined based on available data: Swelling at the injection site¹ Hypersensitivity reactions² Impaired renal function³

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warszawa,

Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605,

https://smz.ezdrowie.gov.pl

Withdrawal periods

Meat and offal:

Cattle, horses, pigs:

- intravenous administration 6 days
- intramuscular administration of up to 4 ml of the product 15 days
- intramuscular or subcutaneous administration of more than 4 ml of the product – 30 days

Milk:

Cattle: 4 days

Special storage precautions

Keep out of the sight and reach of children.

Store below 25°C. Protect from light. Do not freeze. Store in the original, closed package

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

 $Shelf \, life \, after \, first \, opening \, the \, immediate \, package: 28 \, days$

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment

Detailed information on this veterinary medicinal product is available in the Union Product Database

(https://medicines.health.europa.eu/veterinary).

Pack size: 100 ml

Prescription-only veterinary medicine.
To be administered under veterinary supervision.

Marketing authorisation number: 2729/17

SPC: 2023-09-22





¹ Painful, spontaneously resolving oedema at the injection site may appear after intramuscular or subcutaneous injection.

²Elicited especially after rapid intravenous injection.

³ Caused by precipitation of sulphonamide in renal tubules, especially in dehydrated animals, animals with aciduria, or after administration of high doses.

simple ketosis diagnosis in cows

Testoket

Rapid test for detecting ketone bodies

in cow urine or milk

(sodium nitroprusside, ammonium sulfate, anhydrous sodium carbonate)





- detects ketone bodies in urine or milk
- easy-to-perform test
- quick test results

Composition

Sodium nitroprusside, ammonium sulfate, sodium carbonate anhydrous.

Characteristics

Sodium nitroprusside from the test kit reacts with ketone bodies contained in milk or urine, giving colours from pink to violet (depending on ketone body content).

Directions for use

Testoket is a ready-to-use disposable test to be used outside laboratory. Pour 3-4 ml of tested liquid (urine or milk) into a test tube with the reagent, seal with a stopper and shake. Check colour change within up to 2 minutes.

Urine testing

- in healthy cows, reagent and urine do not change colour,
- in cows with subclinical ketosis, reagent and urine turn pink,
- in cows with clinical ketosis, reagent and urine turn violet.

Milk testing:

- in healthy cows and cows with subclinical ketosis, reagent and milk do not change colour,
- appearance of pink to violet colour confirms clinical ketosis.

Warnings

Do not freeze!

Keep out of the reach and sight of children.

User precautions

Toxic effect after consumption and inhaling. Avoid skin and eye contamination. Do the test wearing protective gloves. In case of skin or eye contact, immediately flush the affected site with profuse amount of water.

In case of accidental consumption, provide large amounts of water to drink, induce vomiting.

Immediately seek doctor's advice and present the doctor with packaging.

Neutralize the unused test material or any residues thereof, in accordance with binding safety regulations.

Storage

Store at below 25°C. Protect from light.

Pack content: 10 x 1g Shelf life: 18 months.

For veterinary use.

For self-administration by the animal owner. For animal use only.

Marketing authorization number: PL/WR 000045 Leaflet preparation date: 2013-10-25



Tiamfenikol Biowet Puławy



Injection solution intended for cattle (thiamphenical 250 mg/ml)

Composition

Active substance:

Thiamphenicol - 250 mg

Excipients:

Qualitative composition of excipients and other constituents Propylene glycol

Dimethylacetamide

Clear solution opalescent in brown.

Indications for use

Recommended in the treatment of:

- respiratory diseases caused by Bordetellabronchiseptica, Haemophilus spp., Klebsiella spp., Pasteurella spp.,
- gastrointestinal diseases caused by Escherichia coli, Salmonella spp.,
- metritis caused by Staphylococcus spp., Streptococcus spp., Listeria monocytogenes, Brucella spp., Haemophilus spp., Escherichia coli,
- wounds infected by bacteria of the genus Staphylococcus spp., Streptococcus spp., Proteus spp.

Contraindications

Do not use in case of hypersensitivity to thiamphenicol.

Do not administer simultaneously with beta-lactam antibiotics.

Secial warnings

Special warnings:

The product may be less effective when administered in inflammatory conditions of the reproductive and urinary systems, and peritonitis with severe hepatic and renal dysfunction.

Special caution should be taken when administering the product to animals with end-stage renal failure or with inflammatory and degenerative lesions of the liver.

Special precautions for safe use in the target species:

Administration of the product should be based on results of antimicrobial resistance testing on isolates from sick animals. If this is impossible, applied treatment should be based on the local epidemiological information concerning drug susceptibility of the isolated bacteria.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. In case of contact with skin or mucous membranes—flush the affected area with water immediately.

Pregnancy:

Do not use in pregnant animals.

Lactation:

When using the product during the laying period, observe the 48-hour withdrawal period for milk.

Interaction with other medicinal products and other forms of interaction:

The product acts synergistically with oxytetracycline and macrolides.

Do not administer the product simultaneously with beta-lactam antibiotics.

Overdose:

Laboratory studies in rats have shown evidence of toxicity, with a lethal dose of 10 g/kg body weight in case of per os

administration. For ruminants, lethal dose has not been established. No toxic effect has been found in cattle after administration of doses higher than recommended doses (of up to 60 mg/kg body weight).

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

Target species: cattle

Rare (1 to 10 animals/10 000 animals treated):	Skin rash, lowered red blood cell (erythrocyte) count and haemoglobin. These symptoms may occur during long-term use of high therapeutic doses of the product.
Frequency unknown, cannot be determined based on available data:	Minor pain at the injection site, subsiding spontaneously.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605,

https://smz.ezdrowie.gov.pl

Dosage for each target species, routes and method of administration

The product is intended for intramuscular injection in the following doses:

25-50 mg of thiamphenicol/kg body weight/24 hours.

Administer the product in two separate doses, every 12 hours in the amount of 1-2 ml/20 kg body weight.

Treatment should be administered for 3 to 7 days.

Advice on correct administration

None

Withdrawal period(s)

Meat and offal: 8 days. Milk: 48 hours.

Special storage precautions

Keep out of the sight and reach of

Store below 25°C. Protect from light. Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

Shelf life after first opening the immediate packaging: 28 days.





Tiamfenikol Biowet Puławy



Injection solution intended for cattle (thiamphenical 250 mg/ml)

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Detailed information on this veterinary medicinal product is available in the Union Product Database

(https://medicines.health.europa.eu/veterinary).

Contact details

Poland

Marketing authorisation holder and manufacturer responsible for batch release:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy

Tel./Fax: + 48 (81) 886 33 53, Tel.: + 48 (81) 888 91 00 e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel: + 48 (81) 888 91 33, + 48 509 750 444

Package size: 100 ml

e-mail: biowet@biowet.pl

For animal use only.

Prescription-only veterinary medicine.

To be administered under veterinary supervision.

Marketing authorization: 1550/04 SPC: 2023-09-29





urine under control comfort every day!

Urometin

Openable capsules for cats and small breed dogs supporting urinary tract function (L-methionine, vitamins C and D₃, colostrum)



- helps prevent and support treatment of struvite urolithiasis
- lowers urine pH
- prevents recurrent bladder and urethral infections



Composition per capsule:

bovine colostrum (Colostrum bovinum) > 60% <u>Dietary additive / Amino acid per kg:</u> 3c305 / L-methionine 666,622 mg <u>Dietary additives / Vitamins per kg:</u> 3a300 / Vitamin C 166,656 mg 3a671 / Vitamin D, 30,400 IU

Technological additive / Anti-caking agent per kg:

E 551b / colloidal silica 83,328 mg

Capsule shell:

porcine-bovine gelatin

Sensory additives per kg:

E172 / yellow iron oxide 3,000 mg $\,$

E132 / indigo carmine 1,300 mg

Analytical constituents:

crude protein 58.6%, crude ash 5.9%, crude fat < 1.0%, crude fiber < 0.3%, moisture 4.1%

Properties:

The amino acid **L-methionine** supports the dissolution of struvite stones by lowering urine pH. **Vitamin D**₃ enhances calcium and phosphate absorption and balance in the kidneys. It also contributes to proper immune system function. **Vitamin C** protects cells from free radical damage and aids in urine acidification. **Colostrum** contains immunoglobulins that support the immune system.

Indications:

- As an adjunct in the treatment and prevention of struvite urolithiasis.
- For prophylactic use in recurrent urinary bladder and urethral infections.
- To promote urine acidification.

Administration:

1 capsule twice daily.

The capsule contents may be mixed with other food. If the animal is fed exclusively with dry food, slightly moisten the food so that the powder adheres and is fully consumed. Do not use in combination with other urine acidifying diets. Urometin should be used under veterinary supervision.

Storage conditions:

Store at room temperature in the original packaging. Protect from light and moisture.

Packaging size: 40 openable capsules (376 mg per capsule)

Complementary feed for cats and small breed dogs.

Veterinary identification number: 06148301 Leaflet preparation date: 2024-10-24







Urometin forte

Sprinkle capsules for medium and large breed dogs supporting urinary tract function (L-methionine, vitamins C and D₃, colostrum)





- the amino acid L-methionine lowers urine pH
- vitamin D₃ improves absorption and balances calcium-to-phosphate ratio in the kidneys
- colostrum supports the body's immune system
- vitamin C helps acidify the urine
- brewer's yeast is a natural source of B vitamins









Composition per Capsule

bovine colostrum (Colostrum bovinum) > 60% brewer's yeast from Saccharomyces cerevisiae – 50 mg Dietary Additives / Amino Acids per kg: 3c305 / L-Methionine 677,932 mg Dietary Additives / Vitamins per kg: 3a300 / Vitamin C 101,690 mg

3a671 / Vitamin D₃ 21,700 IU

Technological Additives / Anti-Caking Agent per kg:

E 551b / colloidal silica 67,797 mg

Capsule Shell:

porcine-bovine gelatin Sensory additives per kg:

E172 / red iron oxide 20,000 mg

Analytical Constituents

crude protein: 56.3%, crude ash: 6.15%, crude fat: < 1.0%, crude fiber: < 0.3%, moisture: 3.7%

Properties

The amino acid L-methionine helps dissolve struvite stones by lowering urine pH. Vitamin D_3 enhances calcium and phosphate absorption in the kidneys and supports immune system function. Vitamin C protects cells from free radical damage and aids in urine acidification. Colostrum contains immunoglobulins that support the immune system. Brewer's yeast is a natural source of B vitamins.

Indications

- Supportive treatment and prevention of struvite urolithiasis;
- $Prevention \, of \, recurrent \, bladder \, and \, ure thral \, in fections;$
- Urine acidification.

Dosage and administration

- Dogs 10-25 kg: 2 capsules once daily
- Dogs > 25 kg: 3 capsules once daily

The capsule contents may be mixed with other food. If the diet consists solely of dry food, lightly moisten it to ensure powder adherence and consumption.

Do not use in combination with other urine acidifying feeds. Urometin Forte should preferably be used after consulting a veterinarian.

Storage conditions

Store at room temperature in the original packaging. Protect from light and moisture.

Package size: 40 openable capsules (708.03 mg per capsule)

Complementary feed for medium and large breed dogs.

Veterinary identification number: 06148301 Leaflet preparation date: 2024-10-24







Injection solution intended for dogs, cats and foxes (flumethazone 0.5 mg/ml)

Composition

Flumethasone 0.5 mg / ml

Indications

The medicine is intended to be used in the course of:

- · rheumatoid conditions.
- allergy and inflammation related dermatological conditions,
- · muscle, joint and tendon inflammation,
- respiratory system disorders and mastitis.

Contraindications

Hypersensitivity to flumethasone or any of the components of the product.

General contraindications for the use of glucocorticosteroids also apply to Vecort.

Do not use the drug in cases of: stomach and intestinal ulcers, viral infections, systemic mycoses, pregnancy, hypocalcaemia, osteoporosis, cataracts, glaucoma, poorly healing wounds. Vecort should not be used in the case of bacterial infections until an effective antibiotic therapy has been applied.

Adverse reactions

Like all medicines, Vecort can cause adverse reactions.

An increased demand for water, polyuria and increased appetite may occur.

Stomach and intestinal ulcerations, osteoporosis, growth retardation in young animals may occur. Glucocorticosteroids can cause reversible damage to the liver, hypertension, increased risk of thrombosis, development of cataract, prolonged wound healing.

In long-term treatment with glucocorticosteroids, iatrogenic Cushing's syndrome may occur. Long-term glucocorticosteroid therapy may cause immunosuppression.

A prolonged use of the drug leads to a decrease in adrenal cortex activity and may even lead to atrophy.

Administration of glucocorticosteroids may affect the results of blood laboratory tests causing: increased activity of alkaline phosphatase, increased glucose concentration, decreased concentration total and free $T_{4\prime}$ leucocytosis. Glucocorticosteroids affect the results of tests that assess the activity of the hypothalamo-pituitary-adrenal system and the results of allergic skin tests.

The occurrence of adverse reactions after the administration of this product, or any observed symptoms that cause worry not mentioned in the leaflet (including human reactions due to contact with the medicine), must be reported to a competent veterinarian, the holder of the authorisation or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. A notification form is to be downloaded at https://www.urpl.gov.pl (Veterinary Medicinal Products Division).

Target species

Dog, cat, fox

Dosage and route of administration

Small and medium size dogs, cats, foxes:

0.25 - 0.5 ml intravenously, intramuscularly, subcutaneously 0.25 - 0.5 ml intra-articularly

Large dogs:

0.5 – 1 ml intravenously, intramuscularly, subcutaneously 0,25 – 0,5 ml intra-articularly

The product is administered once; in justified cases, the dose may be repeated after 3 days.

Advice on correct administration

Not applicable.

Withdrawal period(s)

Not applicable.

Special precautions fot storage and transport

Keep this medicine out of sight and reach of children.

Do not store above 25°C. Protect from light.

Shelf-life after the first opening of the packaging: 28 days.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Special warnings and precautions, if necessary

Special warnings for each target species:

Caution should be exercised when using the product in animals with heart failure, diabetes and chronic renal failure.

<u>Special precautions for persons administering the veterinary medicinal product to animals:</u> Protect eyes before being exposed to the product.

In case of accidental self-injection, immediately seek doctor's advice and present the doctor with the information leaflet or package.

Pregnancy and lactation:

Do not use during the whole or part of the pregnancy and in lactating females.

Interaction with other medicinal products and other forms of interaction

Glucocorticosteroids administered in combination with cholinesterase inhibitors may cause increased muscle weakness. Administrated with anticoagulants may reduce or increase their effect. Administered with diuretics and amphotericin B, they may increase the risk of hypokalemia. Used in combination with ephedrine, estrogens, ketoconazole and macrolide antibiotics may intensify and prolong the activity of glucocorticosteroids. Administered together with phenobarbital, phenytoin and rifampicin may weaken the effect of glucocorticosteroids. Glycocorticosteroids weaken the effect of insulin. The combined use of theophylline and glucocorticosteroids changes the activity of both drugs. Glucocorticosteroids should not be used in combination with non-steroidal anti-inflammatory drugs because of the increased risk of gastric ulceration. Glycocorticosteroids increase the risk of

poisoning with drugs such as cyclosporine, erythromycin or cardiac glycosides. The use of glucocorticosteroids should be avoided with vaccines containing live attenuated viruses, as this may lead to increased virus replication.











Injection solution intended for dogs, cats and foxes (flumethazone 0.5 mg/ml)

Overdose (symptoms, emergency procedures, antidotes):

Overdose may cause a decrease in immunity and, consequently, a growing risk of bacterial, fungal and viral infection.

Multiple high doses of glucocorticosteroids may lead to the occurrence of iatrogenic Cushing syndrome (polyuria, polydypsia, polyphagia, truncal obesity, liver enlargement, saggy stomach, hair loss – often symmetrical, thinning of the skin and visible vessels – especially on the abdomen, excessive pigmentation, skin calcifications, muscle weakness and atrophy). Sudden discontinuation of glucocorticosteroids after prolonged treatment (more than 2 weeks) may cause glucocorticosteroid withdrawal syndrome (Addison's disease).

Special precautions fot the disposal of unused veterinary medicinal products or waste materials from the product if applicable

Medicines should not be disposed of via wastewater or with household waste.

Ask your veterinary surgeon how to dispose of unusable medicines. They will ensure better environmental protection.

Other information

For any information about this veterinary medicinal product, please contact the marketing authorisation holder.

Available containers:

A single 20 ml clear glass bottle, packed individually in a cardboard box.

Shelf lie: 2 years

For animal use only.

Prescription-only.

To be administered under veterinary supervision.

Marketing authorization number: 951/99 SPC: 2017-10-24





Vitaminum B_I Biowet Puławy



Injection solution intended for cattle, sheep, horses, chickens, turkeys and dogs (thiamine hydrochloride - 25 mg/ml)

Composition:

1 ml contains:

Active substance:

Thiamine hydrochloride - 25 mg

Excipient:

Phenol 2,25 mg

Target species

Cattle, sheep, horse, chicken, turkey and dog

Indications for use

Vitamin B₁ deficiency and avitaminosis:

- in carnivorous animals on raw fish diet
- in animals artificially nourished using glucose infusions,
- conditions of increased metabolism (fevers, pregnancy, lactation).

Treatment of the following conditions in target species:

- cattle, sheep, horses: reduced viability of newborns.
- dogs: inflammation and paralysis of peripheral nerves, rheumatoid arthritis, nervous form of canine distemper, muscle weakness and digestive disorders leading to vitamin B deficiency
- chickens, turkeys: ataxia, spasms, paralysis, muscle atrophy, polyneuritis.

Contraindications

Do not use in the case of hypersensitivity to the active substance or any of the excipients.

Special warnings

<u>Special precautions for safe use in the target species:</u>
Do not administer the product intravenously as this might cause an anaphylactic shock.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

After accidental contact with eyes, irritation resulting in dacryorrhea might occur. In this case, flush the eye immediately with plenty of lukewarm water or saline solution. Particular caution should be taken to avoid self-injection during administration of the product.

In the case of self-injection, especially intravenous self-injection, an anaphylactic shock, breathing disturbances and temporary hypotension might occur. After self-injection, seek medical help immediately and show the information leaflet or packaging to the doctor.

Special precautions for the protection of the environment: Not applicable.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Laving birds

The product can be used during the laying period.

Interaction with other medicinal products and other forms of interaction:

Administration of amprolium (particularly in turkeys) may cause thiamine deficiency.

Do not use the product together with iron solutions. Avoid administering the drug in combination with plants with high thiaminase content as its excess causes decomposition of vitamin B₁.

Overdose:

Acute poisonings in animals occur only when the recommended dose is exceeded many times. Overdose symptoms include convulsions, cyanosis, breathing difficulties and lower blood pressure. Symptoms of chronic poisoning do not occur as vitamin B₁ is a water-soluble vitamin and it is not accumulated in the body as its excess is excreted in urine.

Thiamine overdose effects have not been observed in clinical practice. No medical intervention is necessary even if the recommended doses are exceeded.

Major incompatibilities:

Sulphates contained in the drinking water may cause decomposition of vitamin B₁. Do not administer the product with neutral or alkaline solutions, as they may cause decomposition of thiamine.

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

Acute pain resulting from the irritating effect of thiamine might occur during administration of the drug (especially in dogs).

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

Dosage for each species, routes and method of administration

Use subcutaneously or intramuscularly once daily in the following doses until clinical symptoms subside: cattle, sheep, horses: 0.5 ml of the product/10 kg b.w., which corresponds to 12.5 mg of vitamin $B_1/10$ kg b.w. chickens, turkeys, dogs: 0.1 ml of the product/1 kg b.w., which corresponds to 2.5 mg of vitamin $B_1/1$ kg b.w.

Advice on correct administration

Do not administer the product intravenously as this might cause an anaphylactic shock.

In order to administer the product properly, follow the instructions contained in this leaflet.

Withdrawal periods

Meat and offal:

cattle, sheep, horses, chickens,

turkeys – zero days

<u>ggs:</u>

turkeys – zero days

Milk:

cattle – zero days

sheep – zero days

dogs – not applicable.









Injection solution intended for cattle, sheep, horses, chickens, turkeys and dogs (thiamine hydrochloride - 25 mg/ml)

Special storage precautions

Keep out of the sight and reach of children. Store below 25°C. Protect from light. Do not freeze. Store in a closed container.

Do not use this veterinary medicinal product after its expiry date given on the label. The expiry date refers to the last day of that month.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Contact details

e-mail: sekretariat@biowet.pl

Marketing authorisation holder and manufacturer responsible for batch release:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel/fax: + 48 (81) 886 33 53, tel: + 48 (81) 888 91 00

Contact details to report suspected adverse reactions:

Biowet Puławy Sp. z o.o. Henryka Arciucha 2 24-100 Puławy

Poland

Tel: + 48 (81) 888 91 33, tel: 509 750.

e-mail: biowet@biowet.pl

Pack size: 50 ml

For animal use only.
Prescription-only.
To be administered under veterinary supervision.

Marketing authorization number: 969/00 SPC: 2023-11-17





Vitaminum Biowet Puławy



Injection solution intended for horses, cattle, pigs, sheep,

dogs, cats and foxes

(ascorbic acid 100 mg/ml)

Active substance and excipient content

Ascorbic acid 100 mg/ml

Therapeutic indications

Vitamin C deficiency, as an adjuvant in antibiotic treatment, in digestive disorders, in pregnancy and exposure to stress, weakness and fatigue. As an adjuvant in urinary infections.

Contraindications

Oxalithiasis.

Adverse reactions

In animals with predisposition for formation of kidney stones, parenteral administration of ascorbic acid may lead to urolithiasis.

Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from https://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Amount to be administered per species, method and route of administration

The product is administered intravenously or intramuscularly in the following daily doses:

Cattle, horses
Swine, sheep
Dogs, cats, foxes
Administer the product for 5-7 days (administration of ½ dose twice a day is recommended).

5-10 mg/kg b.w. i.e. 0.05 − 0.1 ml/kg b.w.
i.e. 0.08 − 0.16 ml/kg b.w.
i.e. 0.08 − 0.16 ml/kg b.w.
i.e. 0.1 − 0.2 ml/kg b.w.

Indications for proper administration

When used intravenously, the product should be warmed to body temperature and injected slowly.

Withdrawal period

Edible tissues:

Horse, cattle, swine, sheep – zero days

Milk:

Cattle, sheep – zero days

Dogs, cats, foxes – not applicable

Special precautions for storage

Keep out of the reach and sight of children.

Store below +25°C. Protect from light. Do not freeze.

Do not use the veterinary medicinal product after the expiry date stated on the label. The expiry date refers to the last day of the given month.

Shelf life after the first opening of the container: 28 days.

Special warnings

Special precautions for use in animals:

Intramuscular administration may lead to local irritation (especially in horses).

Extreme pain may occur during the injection.

Acidic reaction of urine may lead to crystallisation of urates, oxalates and citrates with consequent formation of calculi in the urinary system.

In animals with diagnosed diabetes and in conditions of excessive iron absorption from the gastrointestinal tract,

ascorbates should not be administered in doses higher than the recommended doses.

Parenteral administration of ascorbic acid in doses exceeding indications leads to false positive laboratory test results, indicating the presence of glucose in blood.

Special caution should be taken when administering vitamin C in combination with deferoxamine in old animals. When the two drugs have to be used simultaneously, administration of ascorbic acid is recommended two hours after infusion of deferoxamine.

When used intravenously, the product should be warmed to body temperature and injected slowly.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Accidental self-injection poses no threat to the person administering the drug.

Pregnancy and lactation:

No contraindications for pregnancy or lactation.

Interactions with other medicinal products or other forms of interactions:

Ascorbic acid intensifies the effect of antithrombotic coumarin anticoagulants. It increases iron absorption. Flavonic glycosides intensify the effect of vitamin C.

Ascorbic acid reduces the antibacterial effect of amino glycoside antibiotics and macrolides by increasing the acidic reaction of urine. Simultaneous administration of vitamin C and deferoxamine, an iron-binding drug, used in hemochromatosis and post-transfusion hemosiderosis, may lead to occurrence of iron ions excess, mainly in myocardial cells, which causes arrhythmia and impaired conductivity. Intravenous injection of ascorbic acid shortens the half life of salicylamide.

Simultaneous administration of oxytocin and ascorbic acid reduces the ability of ascorbic acid to penetrate through the placenta into the foetus.

Overdose (symptoms, emergency procedures, antidotes):

Administration of ascorbic acid in doses exceeding indications may lead to urine acidity, which leads to impairment of excretion of weak acids and bases. Vitamin C overdose may cause diarrhoea and reduce absorption of anticoagulant drugs from the gastrointestinal tract.

Multiple administration of ascorbic acid in doses exceeding 4 g may lead to inactivation of vitamin B12, temporary reduction of phagocytic and cidal effects of neutrophils, excessive iron ions absorption and formation of kidney stones

<u>Pharmaceutical incompation in the incompation of t</u>

Ascorbic acid displays chemical incompatibility with sodium bicarbonate, sodium salicylate, sodium nitrate, theobromine, hexamethylenetetramine (methenamine), chlorpromazine hydrochloride, methylprednisolone sodium succinate.









Injection solution intended for horses, cattle, pigs, sheep, dogs, cats and foxes (ascorbic acid 100 mg/ml)

Do not combine ascorbic acid solution with other veterinary medicinal products intended for injection.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Package size: 100 ml Shelf life: 2 years

For animal treatment only.

Subject to medical prescription – prescription drug

Tobe administered under veterinary supervision.

Marketing authorisation number: 991/00 SPC: 2014-12-12







Biowet Puławy Sp. z o.o.

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