Biowet PUŁAWY

100 years OF DRUGS PRODUCTION

Catalogue of veterinary pharmaceuticals

www.biowet.pl

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- About company
- Catalogue of veterinary pharmaceuticals

About company

About Us

Biowet Puławy Ltd. is Polish modern veterinary medicine production plant. Our operations protect health of both animals and people. We supply latest generation effective and safe medicine for veterinary services, farming and breeding sectors. Currently we offer more than 70 preparations, including vaccines, diagnostic preparations, antibiotics, calcium preparations, sulphonamides, antiparasitic preparations, mineral and vitamin supplements and a number of other specialized groups of medicines for multiple species of animals.

Good traditions

For 100 years preparations produced in Puławy have significantly contributed to controlling and keeping in check such dangerous diseases as rinder pest (viral cattle disease), tuberculosis, brucellosis, Newcastle disease, varroosis of honey bees. The 90s were a turning point for the existence of Biowet. An Act of Law titled "Resolution on privatization of the plant in the form of employee-owned company" has been signed. Following completion of the privatization process, in 1997, all employees became shareholders and at the same time also owners of the plant. From the perspective it is clear that company's privatization proved highly successful, as one of the few.

Innovation and prospection

Biowet operations are based on scientific research performed by specialized personnel. We work with the best scientific centres in Poland. The plant uses assistance from specialists in all disciplines of veterinary medicine, in Poland and abroad, from medical schools, institutes, universities and technical universities. Biowet has been working with National Veterinary Institute - National Research Institute in Puławy for many years, in the area of scientific research and national control of immunological products, exercised by NVI under so-called „initial batch control".

Investing in quality and safety

Company's objective is producing safe and effective medicinal products of adequate quality, in line with applicable requirements of pharmaceutical legislation. Products are being improved by implementing new technologies and research methods.

The company has Department of Injection Preparations, which is among the most modern facilities in Poland. Production area is a complex of clean rooms with a system of locks, supplied with filtered air via air-conditioning and ventilation system, ensuring suitable pressure gradient between rooms. Aseptic phases of the process are held in class A/B clean rooms. The Department is fitted out with process installations (injection water, purified water, purified steam, CIP, SIP installations) as well as state-of-the-art process equipment in Good Manufacturing Practice (GMP) standard. Well organized production processes and applied technologies meet the European GMP requirements.

In 2008 a new Department of Biology was opened, dealing with production of immunological products – vaccines and in-vitro diagnostics preparations. The building comprises of clean rooms equipped with a system of man locks and material locks, including air-conditioning and ventilation system providing intake of filtered air as well as pressure barrier. Production compliant with GMP standards is ensured by modern equipment and auxiliary systems (purified water, injection water, purified steam, nitrogen, compressed air). The Department has modules for production of microbial and mycological antigens, module for work with microbes BH-III and medium preparation room. Works





on microbes and aseptic operations are carried out under class A/B laminar exhaust. Modern production technologies comply with GMP standards and the implemented pharmaceutical Quality Assurance System guarantee that good, effective and safe medicinal products are released.

GMP certificates confirm high quality standards compliant with Directive 2003//94/EC for all forms of medicines – injection, biological and non-sterile, granted based on periodic inspections by Senior Inspector of Pharmaceutics.

Achievements

Achievements of Puławy-based Biowet have been noted and awarded by business and social circles in Poland.

Awards granted to the company:

- „Złota Złotówka" [Golden Zloty] for good financial results,
- „Lew Wśród Pracodawców" [Lion Among Employers],
- „Ambasador Województwa Lubelskiego" [The Ambassador of Lubelskie Province]
- „Gazela Biznesu 2002r" [Business Gazelle 2002],
- the reward by Federation of Engineering Associations (NOT) and a number of awards by Ministry of Agriculture. In 2004 three employees received scientific award by Ministry of Agriculture and Rural Development.

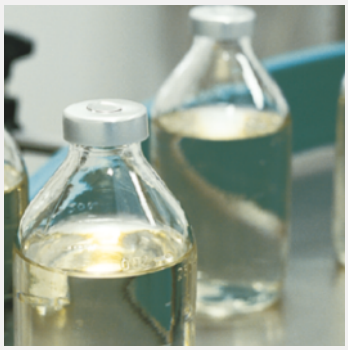
Awards and distinctions for products manufactured by Biowet Puławy Sp. z o.o.:

- Bovitrichovac II - GOLD MEDAL awarded at 3rd „Cattle Farm" Conference/Exhibition in Łomża (2010);
- Rehydrate - GOLD MEDAL awarded at 2nd „Cattle Farm" Conference/Exhibition in Łomża (2009);
- Streptovac - GOLD MEDAL awarded at 11th International Fair of Pigs and Poultry in Poznań (2008);
- Streptovac - NOVELTY Mark awarded at 10th International Fair of Pigs and Poultry in Poznań (2008);
- Thiamphenicol 25% - GOLD MEDAL awarded at 6th „Cattle Farm" International Fair in Poznań (2006);
- Mlek-test - GOLD MEDAL awarded at 4th „Cattle Farm" International Fair in Poznań (2004);
- Mastiprewent - GOLD MEDAL awarded at New Technology Innovation 2003-2004 event.
- Aptovac - GOLD MEDAL awarded at New Technology Innovation 2003-2004 event.

Quality recognized around the world

The most critical test of company's operations is the assessment by its customers. High quality of medicinal products GMP certificates of compliance with Community Directives, granted by competent body, allow expanding our customer base by foreign customers – Biowet cooperates with partners from Lithuania, Ukraine, Belarus, Russia, Hungary, Moldavia, Uzbekistan, Malta, Croatia and Spain.





Alphabetical list of products

Pharmacological list of products

ANALEPTICA
Coffenal (Caffeine)

ANALGETICA ET ANTIPYRETICA
Injectio Pyralgini (Metamizolum Sodium)

ANTIHELMINTICA ET ANTIPARASITICA
Apiwarol® (Amitraze)
Biowar 500 (Amitraze)
Insectin® (Permethrin)

ANTIALLERGICA
Calcigluc®
Calmagluc
Calcii Borogluckonas 25% Inj.

ANTIANAEMICA ET HAEMOPOETICA
Suiferrin 100

ANTIBIOTICA
Enflocyna® (Enrofloxacin)
Enflocyna® Sol. (Enrofloxacin)
Gentamycyna Biowet Puławy (Gentamicin)
Oxyvet (Oxytetracyclinum hydrochloricum)
Tiamfenikol Biowet Puławy (Tiamfenikol)

ANTIRHEUMATICA
Injectio Pyralgini (Metamizole sodium)

CALCIA
Calcigluc
Calcii Borogluconas 25% Inj.
Calem® plus
Calmagluc®

CARDIACA ET CIRCULATORIA
Coffenal (Caffeine)
Inj. Glucosi 40%

DERMATICA
Oticlar
Mastiprewent

DIAGNOSTICA
Brucella abortus antigen
Mlek-Test®
Testoket

HORMONOTHERAPEUTICA
Oxytocinum Biowet Puławy
Depogeston®

SEDATIVA ET HYPNOTICA
Ketamina 10% (Ketaminum hydrochloricum)
Sedazin® (Xylazinum)

VSERA VACCINA
Aptovac
Bovitrichovac®
Mycosalmovir®
PM - VAC®
Salmovir®
Streptovac
Suiferrovit®

SULFONAMIDA
Polisulfalent®
Polisulfamid®

UTERINA
Oxytocinum Biowet Puławy

VITAMINA
Vitaminum B_1 Biowet Puławy
Vitaminum C Biowet Puławy

MINERALO-VITAMINICA ET NOSOTROPHICA
Bioarthrex
Bioarthrex HA
Biohepanex
Biohepanex forte
Bioimmunex canis
Bioimmunex felis
Boviketozin®
Canifos®
Canifos® junior
Canifos® betaglukan
Deodent®
Mastiprewent®
Oticlar®

PREPARATIONS FOR EUTHANASIA
Morbital® (Pentobarbitalum Natrium)

MULTIELECTROLYTICA
Rehydrat®
Elisol

Apiflora

Freeze-dried probiotics for bees

Composition per 125 mg:

Sodium phosphate	55.74 mg
Potassium phosphate	39.04 mg
Lactose	20 mg
Milk proteins (lactalbumin hydrolysate)	20 mg
Gelatin	10 mg
Sodium chloride	6.8 mg
Potassium chloride	0.4 mg

Additives:
Lactic acid fermentation bacteria – *Lactobacillus* ≥1×10^8 CFU/vial
Aromas 2b: Sodium glutamate 20 mg/125 mg
Analytical composition:
total protein 226g/kg, raw fibre 4.12g/kg, raw ash 516g/kg, raw fat - not detected, sodium 109g/kg, phosphorus 86.6g/kg
Properties and indications:
Bacteria from the genus *Lactobacillus* are the major component of the natural gut microbiota of bees in the summer season. Microorganisms contained in the product were isolated from healthy insects belonging to very strong bee families, and selected due to their distinctive probiotic properties and safety. They are capable of colonizing the bee intestine, supporting the digestive processes, and through acidification of their habitats they help protect the bees against infection and development of pathogenic microbes, such as: *Paenibacillus larvae* or *Nosema ceranae*.

Worthy opponent for bacteria and fungi

Apiflora

- *Lactobacillus* genus is capable of colonizing the intestine, thus supporting the digestive processes
- Strengthens the immune system to protect bees against infections and development of pathogens such as *Paenibacillus larvae* or *Nosema ceranae*
- Contributes to extension of bee lifespan and enhances bee colony well-being

Use of the probiotic improves the condition of bee families and contributes to extension of bee lifespan. Supplementation with the probiotic is especially important in the period when bees reduce their contact with the outside environment and naturally-occurring probiotic bacteria.
Directions for use:
Using a disposable syringe, fill 3/4 of the vial with water at room temperature, mix thoroughly until the freeze-dried material is dissolved. Use the obtained suspension in accordance with the intended purpose:
As an additive to sugar syrup used in supplemental spring, summer and autumn feeding.
Mix the content of one vial with sugar syrup cooled down to room temperature, obtained by dissolving 2 kg of sugar in 5 litres of water.
Do not use hot syrup or syrup with higher sugar content, as it has negative effect on microbial viability. Portion the obtained syrup amount into feeders intended for 5 bee families. Repeat the procedure after one week. Syrup prepared in that manner can also be applied directly to the frames, by pouring the syrup onto passageways, 5-10 ml of the syrup per passageway.
As an additive to drinking water for bees.
Dissolve the content of one vial in 10 litres of drinking water for bees.
Apiflora can be repeatedly administered during a year.
Apiflora contains microorganisms comprising the natural gut microbiota of bees; therefore it can be used independently of other products enhancing bee health.
Storage: Store at 2-8°C. During shelf life, freeze-dried probiotics can be stored for 1 month at 15-25°C. Once dissolved, use immediately.
One cardboard box contains 4 vials, each containing 125 mg of the product.
Expiry date: 18 months
Veterinary identification number: α PL 0614003p
2019-02-18

Apiflora was developed with the assistance of scientific units of Maria Curie-Skłodowska University and University of Life Sciences in Lublin.

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Apistym

Immunity stimulating product preventing infections with *Nosema apis* and *Nosema ceranae*

Ingredients in 1000 ml:
4.1.3. Sucrose – 500 g
Additives:
2.b. Ginseng infusion – 50 g in 1000 ml
1.a. Lactic acid – 8.3 ml in 1000 ml
Moisture: 45 %

Analytical constituents:
Total protein 226 g/kg ± 8 g/kg, Crude fibre 4.12 g/kg ± 2.0 g/kg, Crude ash 516 g/kg ± 31 g/kg, Phosphorus 86.6 g/kg ± 5.0 g/kg

Indications
Apistym is recommended to administer in the beehive to enhance bees' immunity. This supplementary feed reduces the spread of infection with *Nosema apis* and *Nosema ceranae*. Application of this supplementary feed during infections, especially with *Nosema apis* and *Nosema ceranae*, reduces pathogen contamination.

Honey bee health improvement

Apistym

- Made from natural ingredients, no withdrawal period for honey
- Boosts resistance of bee colonies to diseases, especially to Nosema disease
- Accelerates bee development
- Autumn supplementary feeding improves bee colony survival rate

Characteristics
Apistym contains ginseng infusion which helps to increase phenol oxidase level (enzyme taking part in immune response), enhancing colony's immunity and vitality. This helps bees to fight pathogens more effectively. Apistym administered in autumn feeding increases colony's survivability in winter and in spring – accelerates its development.

Posology and methods of administration
Shake before use!
Preparing Apistym with sugar syrup solution. Autumn feeding – 4 ml of Apistym per 1 litre of sugar syrup. Sprinkling beeways, stimulative feeding – 20 ml of Apistym per 1 litre of sugar syrup. Syrup temperature should not exceed 50°C.

Autumn usage
Apistym should be administered with sugar syrup solution or prepared bee feed in a dose of 4 ml of the product per 1 litre of syrup. Sugar syrup or feed prepared with Apistym should be administered in colonies during autumn feeding. Adjust feed amount to the colony's strength. Recommended Apistym's dosage per one colony: 40 ml (10 litres of syrup). In case of administering a smaller dosage a supplementary, double sprinkling (at an interval of 7-10 days) of beeways is recommended (solution of Apistym in sugar syrup – 20 ml of the product per 1 litre, 5-10 ml per beeway).

Spring and summer usage
Sprinkle beeways with a solution of Apistym in sugar syrup (20 ml of the product per 1 litre) twice – 5-10 ml per beeway (at an interval of 7-10 days). A solution of Apistym for sprinkling beeways might be administered during stimulative feeding – 0.5-1 litre per colony. Use this dosage during every stimulative feeding.
Apistym might also be administered in a sugar cake – 4 ml of the product per 1 kg of cake per colony.
Once opened use immediately. If the whole product was not used, the opened bottle can be stored in the fridge no longer than 14 days.
Apistym was developed in co-operation with research institutes of University of Life Sciences in Lublin, Maria Curie Sklodowska University in Lublin and Jagiellonian University in Cracow. The product composition is patented and its properties were confirmed by laboratory testing and apiary use.

Bottle volume: 200 ml
Expiry date 12 months
Storage: Store in a cool and dry place.
Veterinary identification number: α PL0614003p
2018-11-19

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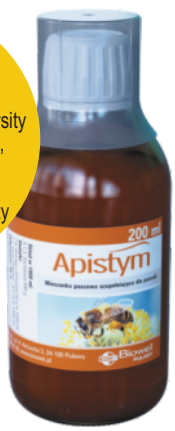
in Cracow.



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BIOWET Biowet PUŁAWY

Apiwarol

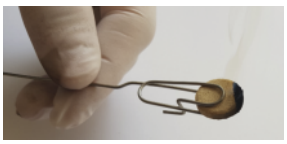
FUMIGATION TABLETS FOR DIAGNOSING
AND COMBATING VARROOSIS IN HONEY BEES

Fumigation tablets
Amitraz 12.5 mg/tablet

Active substance and excipient content
Amitraz 12.5 mg/tablet
Therapeutic indications
Diagnosing and combating varroosis caused by *Varroa destructor.*
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.

How to protect bees against varroosis?

1 tablet / single fumigation of a honey bee colony



1 One tablet contains one therapeutic dose of amitraz sufficient for a single fumigation of a honey bee colony. Hold a tablet with a specially bent wire feeder and set it on fire, blowing off any possibly emerging flame.

2 Introduce the smouldering tablet into the hive through the entrance, and place it on the bottom board beneath the frames.
Use of the tablets in polystyrene beehives requires previous putting of inflammable pads, otherwise the smouldering tablet will damage the bottom board. (1)

3 In hives with polystyrene components, burn the tablets on a strip of metal netting. Place the smouldering tablet on a narrow (3-4 cm) strip of thick metal mesh. Introduce the strip with the smouldering tablet into the hive, and place it on the bottom board beneath the frames.

4 Cover the entrance for 20 minutes. Next, uncover the entrance and check if the tablet has burnt completely. If not, repeat the procedure.

5 Best results in varroosis treatment are obtained if fumigation is applied
- twice in **spring**
- two or three times in **autumn** at intervals of 4-6 days
when there is the smallest amount of encrusted brood in the hive.

Literature:
1) Chorbiński, P.: Eradicating Varroa mite in bees 2nd extended edition, p. 50

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Fumigation tablets
Amitraz 12.5 mg/tablet

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.

Contraindications
Do not use during production of honey intended for human consumption. Do not conduct fumigation at the temperature below +10°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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

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 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.
Interaction with other medicinal products and other forms of interaction: Unknown
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 25 tablets.

Shelf life 1 year

For animal treatment only. Subject to medical prescription – prescription drug. To be administered under veterinary supervision.
Marketing authorisation 740/99

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Aptovac

INACTIVATED VACCINE AGAINST RESPIRATORY TRACT INFECTIONS IN PIGS

Emulsion for intramuscular 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.

Get your animals healthy lungs

Aptovac

- "We should remember that when using subunit vaccines, **the colostrum produced by sows contains antibodies directed only against toxins**. This means that these vaccines fail to protect piglets against App infection in their early days. Therefore, we should use vaccines containing an antigen in the form of killed bacteria, in line with App serotype inducing diseases in the farm. (1)
- Aptovac – effective solution in respiratory tract infection

Porowski, Marian 1,2; Porowski, Michał2; Porowski, Mateusz2; Porowski, Szymon2. **Pleuropneumonia in pigs – experiences in eradicating the disease**
1. Vet-Com Sp. z o.o., Olsztyn
2. „Animal" Private Veterinary Practice, Pobiedziska

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
Weaners:
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.

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Biowet PUŁAWY

Aptovac

INACTIVATED VACCINE AGAINST RESPIRATORY TRACT INFECTIONS IN PIGS

Emulsion for intramuscular injection for pigs.

Contraindications
Do not vaccinate sick animals.

Adverse reactions
A rare adverse reaction is body temperature increased by 2°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 (Department of Veterinary Medicinal Products).

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.

Available pack sizes:
One (type II) glass bottle, containing 100 ml of the vaccine, with a rubber stopper and aluminium cap, wrapped in a cardboard box.

Shelf life 1 year.

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

2014-07-15 SPC

Marketing authorisation holder
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Avituberculin

FOR COMPARATIVE INTRADERMAL TUBERCULIN TESTS IN CATTLE

Solution for injection for cattle

Statement of active and other substances 1 ml of the product contains:
Active substance:
avian tuberculin, purified protein derivatives from the culture of *Mycobacterium avium* D_4ER 25 000 IU
Excipient: phenol 5 mg
Indications
The product is used for comparative intradermal tuberculin tests in cattle.
Dosage for each species, route and method of administration
Administer 0.1 ml of the product (corresponding to 2500 IU of tuberculin) via the intradermal route.
Advice on correct administration
Tuberculin testing technique
Administer 0.1 ml of the product (corresponding to 2500 IU of tuberculin) via the intradermal route.
While performing the comparative tuberculin test, the site for the injection of avian tuberculin should be about 10 cm from the crest of the neck, and the site for injection of the bovine tuberculin about 12.5 cm lower. In young animals in which there is not room to separate the sides sufficiently on one side of the neck, one injection should be made on each side of the neck at identical sites in the centre of the middle third of the neck.
Skin 5 cm around the planned injection site should be free of any lesions. Before administering the product, the injection site should be marked by clipping a small cross with arm length of 2-3 cm. Next, a fold of skin with the clipped hair should be taken between the forefinger and thumb and measured with a calliper with accuracy of 0.1 mm. Tuberculin dose should be injected in the manner ensuring intradermal depositing of tuberculin. The needle, bevel edge outwards, should be inserted obliquely and intradermally. A correct injection should be confirmed by palpating a pea-like swelling at the injection site.
Tuberculin testing results should be recorded 72 (± 4) hours after injection. The injection site should be inspected and the fold of skin should be measured again.
Interpretation of reactions
The interpretation of reactions to tuberculin administration in cattle should be based on clinical observations and differences in skin-fold thickness at the injection site.
Comparative tuberculin test – single, intradermal injection of bovine tuberculin and single, intradermal injection of avian tuberculin made at the same time, and reading out of results:

a) positive reaction (+): increase in skin thickness at the bovine site of injection which is more than 4.0 mm greater than the reaction at the avian site of injection, or the presence of clinical signs;
b) inconclusive reaction (+/-): positive or inconclusive reaction with increase in skin thickness at the bovine site of injection which is 1.0 to 4.0 mm greater than the reaction at the site of avian injection, and absence of clinical signs;
c) negative reaction (-): negative reaction at the bovine site of injection or positive or inconclusive reaction at the bovine site of injection which is less than or equal to the reaction at the avian site of injection, with absence of clinical signs.

The official procedure for assessing tuberculin test results and treatment of animals is set out in the instruction of the Chief Veterinary Officer.
Contraindications None
Adverse reactions None confirmed. 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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).
Withdrawal period
Meat and offal - zero days.
Milk - zero days.
Special precautions for storage
Keep out of the reach and sight of children. Store in a refrigerator (2 - 8°C). Protect from light. Do not freeze. Shelf life after first opening the immediate packaging: 24 hours. Do not use after the expiry date stated on the label.
Special warnings
Special warnings for each target species:
Do not use the product in animals less than 6 weeks of age. It is not recommended to perform another tuberculin test before 42 days after the last administration of the product.
Do not use in the period spanning 2 weeks before parturition and 2 weeks post-partum. Do not use the product during treatment with corticosteroids.
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, thoroughly wash the affected area 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 data is available to state that the product has any adverse effect on pregnancy and lactation.
Due to increased risk of falsely negative results, tuberculin tests should not be performed in the period spanning between 2 weeks before parturition and 2 weeks post-partum.
Interaction with other medicinal products and other forms of interaction:
Concurrent administration of corticosteroids or other immunosuppressants may weaken the reaction to tuberculin and lead to emergence of falsely negative results.
Overdose (symptoms, emergency procedures, antidotes) if necessary:
The only effect of multiple administration of the product is decreased animal reactivity to subsequent tuberculin doses. This poses no threat to the life or health of animals.

Marketing authorisation holder
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Biowet PUŁAWY

Avituberculin

FOR COMPARATIVE INTRADERMAL TUBERCULIN TESTS IN CATTLE

Solution for injection for cattle

Incompatibilities:
In the absence of incompatibility studies, this veterinary medicinal product should 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 waste water or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help protect the environment.

Package size

6 ml vial, containing 25 doses. Cardboard box containing 1 or 5 vials (1 x 25 doses, 5 x 25 doses).

Shelf life 2 years

For animal treatment only. To be supplied only on veterinary prescription. To be administered under veterinary supervision.

Marketing Authorisation 2627/17

SPC 2017-02-27

Marketing authorisation holder
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Biowet PUŁAWY

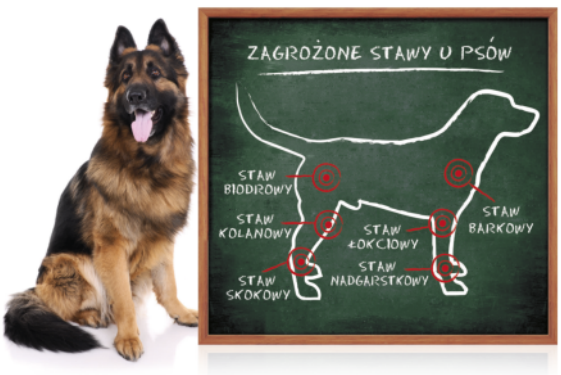
Bioarthrex

TABLETS AIDING REGENERATION OF ARTICULAR CARTILAGE

Supplementary feed for dogs

Ingredients:
Glucosamine hydrochloride, chondroitin sulfate, dicalcium phosphorate, wheat/potato starch, processed animal protein, brewer yeast, pork gelatin, magnesium stearate.
Additives:
Sensory additive (2 b)
Harpagophytum procumbens (extract) 60 000 mg/kg
Nutritional additives (3 a)
L – carnitine 5 000 mg/kg
Ascorbic acid 5 000 mg/kg
Nutritional additive (3 b)
Manganese sulphate 400 mg/kg
Analytical constituents:
total protein 14.28 %, crude fat 1.02%, crude fibre below 1%, crude ash 27.49%

Save your dog joint pain



Bioarthrex

- Strengthens and regenerates articular cartilage
- Prevents cartilage micro-damage in joints
- Has analgesic and anti-inflammatory effect
- Flavoured tablets lure dogs with their aroma

Properties and indications:
Bioarthrex is a supplementary feed protecting joints and bones of dogs. It is especially recommended for use in breeds with a higher risk of joint and musculoskeletal system diseases, and in older animals. Chondroitin and glucosamine are the basic components of extracellular matrix of cartilage. Participate in regeneration of the articular cartilage, prevent articular microdamage occurring during intense physical effort and, consequently, prevent inflammatory conditions. *Harpagophytum procumbens* extract is an anti-inflammatory agent. Ascorbic acid and manganese are necessary in the synthesis of collagen which is a component of the intercellular substance.
Posolgy:
Administer tablets directly into the mouth or with other feed.

Animal body weight	Posology during the first 4-6 weeks (no. of tablets / day)	Continued administration (no. of tablets / day)
below 30 kg	2	1
30 - 60 kg	3	1.5
above 60 kg	4	2

Storage: *STORE AT ROOM TEMPERATURE IN A DRY PLACE.*
CAUTION: *This compound feed contains animal-derived protein which is prohibited in ruminant feed.*
Additional information:
1 tablet contains: Glucosamine hydrochloride – 500 mg, chondroitin sulfate – 400 mg, *Harpagophytum procumbens* (extract) – 150 mg, L-carnitine – 12.6 mg, Ascorbic acid – 12.5 mg
Bioarthrex contains no preservatives.
Shelf life 18 months
For animal treatment only.
Net weight: 2.5 g. Pack size: 75 tablets
Veterinary approval number: **06148301**
Date of the leaflet - 09.11.2017 r

Marketing authorisation holder
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e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Bioarthrex HA

TABLETS AIDING REGENERATION OF ARTICULAR CARTILAGE

Supplementary feed for dogs

Ingredients:
Glucosamine hydrochloride, chondroitin sulfate, dicalcium phosphorate, wheat/potato starch, processed animal protein, brewer yeast, pork gelatin, magnesium stearate.

Additives in 1 kg:

Harpagophytum procumbens (extract)	120 000 mg
L – carnitine	5 040 mg
Ascorbic acid	5 360 mg
Manganese sulphate	400 mg

Regeneration of articular cartilage

Bioarthrex HA

- Enhances regeneration of articular cartilage, ensuring proper functions of the joints and mobility of your dog
- Chondroitin and glucosamine are involved in regeneration of the cartilage, they prevent joint micro-damage
- Sodium hyaluronate ensures essential hydration of the joints
- *Harpagophytum procumbens* extract has anti-inflammatory effect

Analytical constituents:
total protein 13.95 %, crude fat below 1%, crude fibre below 1%, crude ash 20.44%

Properties and indications:
Bioarthrex HA is a supplementary feed protecting joints and bones of dogs. It is especially recommended for use in breeds with a higher risk of joint and musculoskeletal system diseases, and in older animals. Bioarthrex HA contains ingredients capable of regenerating articular cartilage which affect the proper function of joints and motor skills of a dog. Chondroitin and glucosamine participate in regeneration of the articular cartilage, prevent articular microdamage occurring during intense physical effort and, consequently, prevent inflammatory conditions. Sodium hyaluronate provides necessary lubrication of the joints. It serves as a shock absorber reducing friction between moving bones. *Harpagophytum procumbens* extract is an anti-inflammatory agent. Ascorbic acid and manganese are necessary in the synthesis of collagen which is a component of the intercellular substance.

Posology: Administer tablets directly into the mouth or with other feed.

Animal body weight	Posology during the first 4-6 weeks (no. of tablets / day)	Continued administration (no. of tablets / day)
below 30 kg	2	1
30 - 60 kg	3	1.5
above 60 kg	4	2

Storage: Store at room temperature in a dry place.
CAUTION: This compound feed contains animal-derived protein which is prohibited in ruminant feed.
One tablet (2.5 g) contains:
Glucosamine hydrochloride – 500 mg, chondroitin sulfate – 400 mg, *Harpagophytum procumbens* (extract) – 300 mg, sodium hyaluronate – 15 mg, L-carnitine – 12.6 mg.
For animal treatment only.
Shelf life: 18 months
Bioarthrex HA contains no preservatives.
Net weight: 2.5 g. Pack size: 75 tablets
Veterinary approval number: 06148301
Date of the leaflet - 08.11.2017 r

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

BIOWET Biowet PUŁAWY

Biohepanex

Phospholipids, ornithine feed supplement for dogs and cats (in capsules)

Ingredients:
wheat starch, pork and beef gelatin (*capsule shell*), magnesium stearate

Additives

Technological additives (anti-caking agents)

Microcrystalline cellulose (E 460)	132 013 mg/kg
Colloidal silica (E 551b)	6 600 mg/kg

Technological additive (emulsifier)

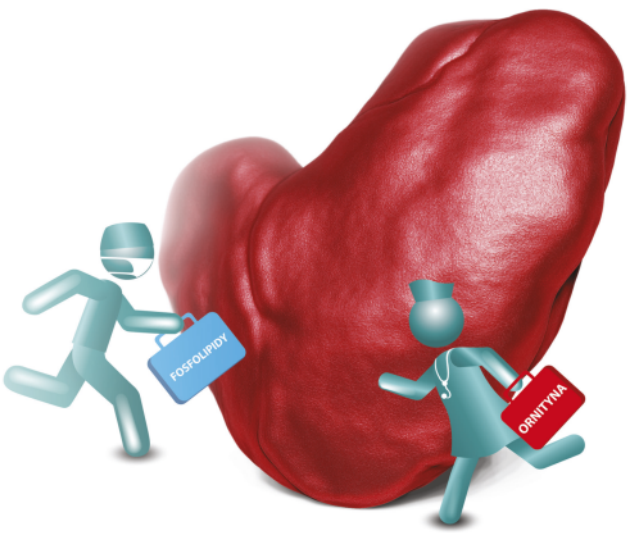
Lecithin (E 322)	132 013 mg/kg

Additional information:
One capsule contains 40 mg of soy lecithin containing phosphatidylcholine.
In addition to substances and feed additives listed as ingredients, Biohepanex contains ornithine – 40 mg per capsule.
Before using Biohepanex, it is advisable to consult a veterinarian.

Analytical constituents:
total protein 38.3%, crude fat 13.3%, crude fibre 7.4%, crude ash 2.4%

Properties and indications:
Phospholipids contained in soy lecithin protect liver cells by supporting their regeneration.
They participate in digestion of fats and absorption of vitamins A, D, E and K.
They reduce the process of liver fibrosis and prevent fatty degeneration and cirrhosis of the liver.
Ornithine supports liver functions, consequently accelerating detoxification of the body.

Here comes regeneration



Biohepanex

Phospholipids, ornithine

- Enhances natural liver functions
- Regenerates liver
- Protects liver cells

Biohepanex is recommended for:

dogs and cats:

- in hepatic insufficiency and functional disorders of the liver;
- in impaired digestion;
- as support in bile duct diseases;

cats

- with symptoms of hepatic encephalopathy and to weak cats due to prolonged lack of food intake

Posology: 1 capsule per 4 kg b.w./day. Capsule contents can be mixed with fodder.
Storage Store in a dry cool place.
Shelf life 18 months
Pack size: 40 capsules. Net weight: 363 mg
Veterinary approval number: 06148301
Date of the leaflet- 25.10.2017

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Biohepanex forte

CAPSULES SUPPORTING LIVER FUNCTIONS

Phospholipids, ornithine capsules for dogs supporting liver health

Ingredients:
Wheat starch, pork and beef gelatin (capsule shell), magnesium stearate

Additives:

Technological additives (anti-caking agents)

Microcrystalline cellulose E 460	50 505 mg/kg
Colloidal silica E 551b	3 367 mg/kg

Technological additive (emulsifier)

Lecithin E 322	252 525 mg/kg

Additional information:
One capsule contains 150 mg of soy lecithin containing phosphatidylcholine. In addition to substances and feed additives listed as ingredients, Biohepanex forte contains ornithine – 150 mg per capsule. Before using Biohepanex forte, it is advisable to consult a veterinarian.

Analytical constituents:
total protein 46.44%, crude fat 24.1%, crude fibre 3.3%, crude ash 3.3%

Properties and indications:
Phospholipids contained in soy lecithin protect liver cells by supporting their regeneration. They participate in digestion of fats and absorption of vitamins A, D, E and K. They reduce the process of liver fibrosis and prevent fatty degeneration and cirrhosis of the liver. Ornithine supports liver functions, consequently accelerating detoxification of the body.

Best composition for the liver

Phospholipids

- Protect liver cells, promoting their regeneration
- Are involved in fat digestion and absorption of fat-soluble vitamins: A, D, E, K
- Limit hepatic fibrosis and prevent fatty liver disease and cirrhosis

Ornithine

- Ornithine, as the starting point for the synthesis of polyamines, plays an important role in stimulating liver regeneration
- Supports natural liver functions, accelerating detoxication of the organism

Biohepanex forte is recommended for dogs:

- in hepatic insufficiency and functional disorders of the liver;
- in impaired digestion;
- as support in bile duct diseases;

Posology:
1 capsule per 15 kg b.w./day. Capsule contents can be mixed with fodder.
Storage Store in a dry cool place.
Shelf life 18 months
Pack size: 45 capsules. Net weight: 594 mg
Veterinary approval number: 06148301
Date of the leaflet-19.10.2017

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Bioimmunex canis

IMMUNITY BOOSTER CAPSULES

β1,3/1,6-D-glucan 20 mg feed supplement for dogs (in capsules)

Ingredients
Beta-1,3/1,6-D-glucan (derived from *Saccharomyces cerevisiae*), wheat starch, pork and beef gelatin (*capsule shell*), magnesium stearate.

Additives
Technological additives (anti-caking agents)

Microcrystalline cellulose (E 460)	204 402 mg/kg
Colloidal silica (E 551b)	6 289 mg/kg

Analytical constituents:
total protein 79.0%, crude fat 0.5%, crude fibre 12.7%, crude ash 1.0%

One capsule contains
Beta-1,3/1,6-D-glucan
Excipients

Immunity boost

Bioimmunex canis

- Strengthens immune system
- Protects against infections
- Neutralizes free radicals

Properties and indications
Beta-1,3/1,6-D-glucan is a natural completely purified polysaccharide, isolated from the cellular walls of *Saccharomyces cerevisiae*. Beta-glucan strongly stimulates the immune system through activation of macrophages, lymphocytes and neutrophils. Macrophages play a basic role in anti-infectious immunity, in removal of abnormal or dead cells, as well as foreign bodies from the body.
Beta-glucan reinforces the effect of other preparations used in treatment (antibiotics, antifungal and antiparasitic agents), accelerates tissue regeneration, has anticancer properties and is an antioxidant – it neutralises free radicals.
Bioimmunex canis is recommended for dogs:

- as preventive measure in order to reinforce natural immunity;
- as support in treatment of infectious diseases, neoplasms, and in convalescence;
- in stressful situations (exhibitions, journeys, change of environment).

Posology
1 capsule per 20 kg b.w. / day
Capsule contents can be mixed with fodder. In the case of a larger number of capsules, it is recommended that the dose is divided into 2-3 times.
Storage Store in a dry cool place.
Shelf life 2 years
Pack size: 40 capsules. Net weight: 353 mg.
For animal treatment only.
Veterinary approval number 06148301
Date of the leaflet - 25.10.2017.

Marketing authorisation holder
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Biowet PUŁAWY

Bioimmunex felis

IMMUNITY BOOSTER CAPSULES

β1,3/1,6-D-glucan 10 mg feed supplement for cats (in capsules)

Ingredients:
Beta-1,3/1,6-D-glucan (derived from *Saccharomyces cerevisiae*), wheat starch, pork and beef gelatin (*capsule shell*), magnesium stearate
Additives
Technological additives (anti-caking agents)

Microcrystalline cellulose (E 460)	283 300 mg/kg
Colloidal silica (E 551b)	5 700 mg/kg

Analytical constituents:
total protein 79.0%, crude fat 0.5%, crude fibre 12.7%, crude ash 1.0%
One capsule contains
Beta-1,3/1,6-D-glucane – 10 mg
Excipients

Immune system activator

Bioimmunex felis

- Strongly stimulates immune system
- Powerful stimulation to cat's immune system
- Increases activity of the cells of the immune system
- Accelerates tissue regeneration

Properties and indications
Beta-1,3/1,6-D-glucan is a natural completely purified polysaccharide, isolated from the cellular walls of *Saccharomyces cerevisiae*. Beta-glucan strongly stimulates the immune system through activation of macrophages, lymphocytes and neutrophils. Macrophages play a basic role in anti-infectious immunity, in removal of abnormal or dead cells as well as foreign bodies from the body.
Beta-glucan reinforces the effect of other preparations used in treatment (antibiotics, antifungal and antiparasitic agents), accelerates tissue regeneration, has anticancer properties and is an antioxidant – it neutralises free radicals.
Bioimmunex felis is recommended for cats:

- as a preventive measure to reinforce natural immunity;
- as support in treatment of infectious diseases, neoplasms, and in convalescence;
- in stressful situations (exhibitions, journeys, change of environment).

Posology
1 capsule / for cat.
Capsule contents can be mixed with fodder.
Storage Store in a dry cool place.
Shelf life 2 years
Pack size: 40 capsules. Net weight: 353 mg.
For animal treatment only.
Veterinary approval number: 06148301
Date of the leaflet - 25.10.2017.

Pet-friendly method of administration

Marketing authorisation holder
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e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Bioskinex canis

CAPSULES IMPROVING SKIN AND HAIR CONDITION

Capsules improving skin and coat condition for dogs
Supplementary dog feed

Ingredients:
7.7.1. *Cistus incanus* extract
12.1.5. Yeast extract (*Saccharomyces cerevisiae*)
9.12.1. Bovine and poultry gelatine (capsule shell)

Additives:

Zinc sulfate (3b)	273 224 mg/kg
Horsetail extract (*Equisetum arvense*) (2b)	54 645 mg/kg
Calcium pantothenicum (3b)	8 197 mg/kg
Biotin (3a)	5 464 mg/kg
Technological additives (anticaking agents):	
Microcrystalline cellulose (E 460)	136 612 mg/kg
Amorphous silica (E 551B)	13 661 mg/kg
Sensory additives (capsule shell colouration):	
Titanium dioxide (E 171)	4 153 mg/kg
Indigo carmine (E 132)	109 mg/kg

Analytical constituents:
total protein less than 5%, crude fat less than 1%, crude fiber 9.97%, crude ash 21.97%
One capsule contains: Biotin 2 mg, Zinc sulfate 100 mg, Calcium pantothenicum 3 mg, Yeast extract 10 mg, *Cistus incanus* dry extract 100 mg, Horsetail dry extract (*Equisetum arvense*) 20 mg, Fillers.

Single solution for hair, skin and claws

Bioskinex canis

- Reduces treatment time of selected skin disease
- Improves appearance of fur and skin
- Easy to apply
- Well-tolerated by animals
- Highly popular among pet owners

Characteristics and indications
Supplement ingredients – biotin, zinc sulfate and calcium pantothenicum – increase density and elasticity of hair. Biotin protects skin and hair thanks to sulphur molecules. It takes part in the synthesis of carbohydrates, proteins and fatty acids, which plays a role in maintaining healthy skin. Zinc participates in skin cell proliferation and wound healing and it is vital in regulating sebaceous gland activity. Calcium pantothenicum is engaged in hair growth, tightening epidermal barrier, tissue regeneration, and anti-inflammatory activity. Yeast cells are the source of B vitamins, which take part in the metabolism of unsaturated fatty acids. Horsetail is the source of silicon, which aids in the production of collagen. *Cistus incanus* contains antioxidative polyphenols.

Bioskinex canis is recommended for dogs:
- As a preventive measure during coat shedding.
- As a support in skin diseases manifested by dry, dull skin, brittle hair and excessive epidermis shedding.
- To improve the condition of cracking and brittle nails.

Posology and method of administration:
1 capsule per 10 kg b. w./day. Capsule contents can be mixed with fodder. The dosage might be divided into 2-3 parts to be taken during the day.
Storage Store in a dry and cool place.
Shelf life: 12 months
Package size: 40. **Capsule net weight:** 366 mg.
For animal treatment only
Veterinary approval number: 06148301
2018-02-12

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Biourinex canis

CAPSULES SUPPORTING LOWER URINARY TRACT FUNCTIONS

Supplementary dog food

Composition:
Glucosamine hydrochloride
Additives:

Cranberry extract (2b)	388500 mg/kg
Soy lecithin (E 322)	129500 mg/kg
Parsley extract (2b)	64800 mg/kg
Colloidal silica (E551b)	6500 mg/kg

Analytical constituents:
crude protein 14%, crude fat 14%, crude fibre below 1%, crude ash 3.3%
One capsule contains:

Glucosamine hydrochloride	200 mg
Cranberry extract	300 mg
Parsley extract	50 mg
Soy lecithin	100 mg

Fillers

To treat lower urinary tract disorders

Biourinex canis

- Cranberry extract minimizes bacteria's capability of colonizing the urinary tract
- Glucosamine protects the mucosa of the urinary tract, soothing inflammations
- Parsley extract, owing to its diuretic effect, contributes to mechanical purification of the urinary tract

Properties and indications:
It is advised to administer Biourinex canis after seeking veterinarian's advice:
- in lower urinary tract infections
- as a supplement in treating urolithiasis
- as a supplement after kidney stone surgery

Posology:
1 capsule per 10 kg b.w. /day. Capsule contents can be mixed with fodder.
Storage:
Store in a cool dry place.
Pack size: 45 capsules. **Net weight:** 772 mg.
Shelf life: 1 year.
Veterinary approval number: 06148301
For animal treatment only.
2017-11-09

Pet-friendly method of administration

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Biourinex felis

CAPSULES SUPPORTING LOWER URINARY TRACT FUNCTIONS

Supplementary feed for cats

Composition:
Glucosamine hydrochloride
Additives:

Cranberry extract (2b)	346300 mg/kg
Soy lecithin (E 322)	138500 mg/kg
Parsley extract (2b)	69300 mg/kg
Valerian extract (2b)	69300 mg/kg
Lemon balm extract (2b)	69300 mg/kg
Colloidal silica (E551b)	6900 mg/kg

Analytical constituents:
crude protein 9%, crude fat 15%, crude fibre below 1%, crude ash 3.8%
One capsule contains:

Glucosamine hydrochloride	100 mg
Cranberry extract	250 mg
Parsley extract	50 mg
Soy lecithin	100 mg
Valerian extract	50 mg
Lemon balm extract	50 mg
Fillers	

For use in lower urinary tract problems

Biourinex felis

- Contains substances of natural origin
- Is highly effective in preventing and supporting treatment of lower urinary tract problems
- *Valeriana officinalis* and *Melissa officinalis* extracts have a soothing effect contributing to reduction of stress which, especially in cats, is regarded as one of the main causes of bladder inflammations
- Easy to apply and safe

Properties and indications:
It is advised to administer Biourinex felis after seeking veterinarian advice:

- in lower urinary tract infections
- as a supplement in treating urolithiasis
- as a supplement after kidney stone surgery

Posology: 1 capsule a day. Mix capsule contents with fodder.
Storage: Store in a cool dry place.
Pack size: 45 capsules. **Net weight:** 722 mg.
Shelf life: 12 months.
For animal treatment only.
Veterinary approval number: 06148301
Date of the leaflet - 09.11.2017

Pet-friendly method of administration

Marketing authorisation holder
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e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Biowar

FOR COMBATING VARROOSIS IN HONEY BEES

Strips for placing in honey bee hives
Amitraz 500 mg/strip

Active substance and excipient content
1 strip contains:
Active substance:
Amitraz 500 mg
Therapeutic indications
Combating varroosis in bees.
Amount to be administered per species, route and method of administration
Product for hanging in bee hives in a dose: 2 strips per hive.
Instructions for use

How to protect bees against varroosis?

2 strips/1 honey bee family

1 Place Biowar strips in aisles with the highest bee activity, as these are locations with the largest amount of parasites. By introducing a stick into a specially prepared hole in each strip, we can easily hang the strip in the frame-separating aisles.

2 Expand the aisles before hanging the strips to provide free bee access from both sides. In hives with side bars between the frames, this may be done by placing two bars per one frame-separating aisle.

3 In vertical hives, hang the strips at a lower level to locate them in the area of the highest bee activity. If bee activity inside the hive is away from the strips, change strip location to where the bees swarm the most. Do not hang the strips in very narrow aisles or in the nest peripheries, as they are not densely populated by the bees. (1)

4 Leave the strips in a hive for 8 weeks, then remove. It is recommended to conduct treatment in all hives of a given apiary at the same time.
Use the strips immediately after opening. Do not re-use the strips.
Do not use the product after the use-by date.

5 Biowar is intended for hanging in bee hives in a dose: **2 strips per 1 honey bee colony.**
Spring treatment – before the first commercial nectar
Autumn treatment – after the final harvest of honey (end of summer/autumn).

Literature:
1) Chorbiński, P.: Eradicating Varroa mite in bees 2nd extended edition, p. 51

Biowar strips are vacuum-packed

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Strips for placing in honey bee hives

Amitraz 500 mg/strip

Place strips in frame-separating aisles with the highest bee activity. Hang strips to provide free bee access from both sides, which is 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 should be removed after the maximum of 8 weeks. Do not re-use the strips. It is recommended to conduct treatment in all hives at the same time. Recommended period of treatment: after the final honey extraction (end of summer/autumn) and in spring before the first pollen harvest. Comply with recommended treatment periods and amounts to be administered.

Contraindications

None

Adverse reactions

Unknown.

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

Withdrawal period

Honey – zero 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, in the original, tightly closed package. Shelf life after first opening the immediate packaging: use up immediately. Do not use this veterinary medicinal product after the use-by date given on the label.

Special precautions

Special warnings for each target species:

All colonies in the hive must be treated at the same time.

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

Wear protective gloves when handling the strips. Do not eat, drink, or smoke while applying the strips. While using the product, do not allow contact with skin and eyes. After procedure is complete, wash hands with warm water and soap. Do not allow contact of the product with food.

Interaction with other medicinal products and other forms of interaction:

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

Overdose (symptoms, emergency procedures, antidotes):

While applying doses 5-times higher than recommended for the period of 6 weeks, no adverse reactions were observed.

Pharmaceutical incompatibilities: Unknown

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

Unused veterinary medicinal product or waste materials derived from the use of such products such be disposed of in accordance with applicable regulations. Amitraz is toxic for fish, therefore attention must be paid to prevent disposal of the product to bodies of water or water currents.

Shelf life 18 months

Type and content of immediate packaging

Cardboard box containing 10 strips placed inside in a PET/Aluminum/PE sachet.

For animal treatment only

Subject to medical prescription – prescription drug.

To be administered under veterinary supervision

Marketing Authorization no.: 2085/11

2016-06-08 SPC

Biowar strips are vacuum-packed

Marketing authorisation holder

Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Boviketozin

FOR PREVENTING AND SUPPORTING PROPER TREATMENT OF KETOSIS IN COWS AND SHEEP

Dietetic feeding stuff for dairy cows and sheep

Composition
Propylene glycol 99.7% (997ml/l)
Dietetic feed additives

Potassium iodide (trace element 3b E2 iodine)	0.2%	(Iodine [I] 1345 mg/l) (Potassium [K] 415 mg/l)
Cobalt (II) sulphate x 7 H_2O (trace element 3b E3 cobalt)	0.1%	(Cobalt [Co] 207 mg/l)

Properties and indications:
Boviketozin is used to supplement the diet of cows with high milk yield and sheep with easily digestible carbohydrates. The use of the supplement is particularly recommended at the peak of lactation when the body's demand for carbohydrates necessary for production of milk components increases. The shortage of carbohydrates in the feed, with their concomitant increased use for the purposes of lactation, may cause impaired metabolism manifesting itself in the occurrence of ketone bodies. Boviketozin improves the digestibility of structural fibre, reduces the incidence of ketosis, improves feed intake by animals, normalises impaired lactation, stabilises fat and protein content in milk.

Fast ketosis response

Boviketozin

- Supports proper treatment of ketosis and reduces prevalence of the disease
- Improves feed intake by animals
- Regulates disturbed milk ejection

Posology
Boviketozin is administered to:
Cows – in the last 6 weeks before labour and between the 3rd and 6th week after labour at a dose of 250 ml once daily.
Sheep – 60-100 ml once a day for the first 3 weeks after labour.
Boviketozin is used as a mixture with water of feed. In the case of appetite impairment and an aversion to consuming feed, the non-diluted preparation can be administered directly into the mouth. Consult a veterinary doctor before use.
Storage conditions:
Store at a temperature below +25°C, in a dark and dry place in original, tightly closed container.
Shelf life 24 months
Available containers 1000 ml
Veterinary approval number Biowet Puławy Ltd., αPL0614003p
Date of the leaflet - 09.11.2015 r.

Marketing authorisation holder
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Biowet PUŁAWY

Bovitrichovac

INACTIVATED VACCINE AGAINST DERMATOPHYTOSIS IN CATTLE

Inactivated vaccine against dermatomycosis in cattle

Quantitative and qualitative composition of active substances
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.

Ruthless for dermatophytosis, prevent and treat

Bovitrichovac

- Preventive use of vaccines containing inactivated suspension of *Trichophyton verrucosum* culture is one the most effective methods of combating/fighting the disease. Bovitrichovac powerfully induces cellular immune responses which plays the essential role in eliminating the infection.
- In young fatteners, the disease reduces their body mass and decreases their value in use
- Dermatophytosis in adult bovine animals may be considerably persevering
- Immunity after double administration of the vaccine ranges from 9 to 12 months

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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).
Withdrawal period Zero days.
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.
Available containers 250 ml
Shelf life 12 months
Subject to medical prescription – prescription drug. For animal treatment only.
Marketing authorisation 486/98
SPC 2014-04-03

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Bovituberculin

FOR DIAGNOSING TUBERCULOSIS IN CATTLE

Solution for injection for cattle

Statement of active and other substances
1 ml of the product contains:
Active substance:
bovine tuberculin, purified protein derivatives from the culture of *Mycobacterium bovis* AN $_5$ 32 500 IU
Excipient: phenol 5 mg
Indications
The product is used to diagnose tuberculosis in cattle more than 6 weeks of age, infected by *Mycobacterium bovis*.
Dosage for each species, route and method of administration
Apply intradermally 0.1 ml dose of product, which corresponds to 3250 IU of tuberculin.
Advice on correct administration
Tuberculin testing technique
Administration site for a single tuberculine test should be located at the interface of the front and middle thirds of the neck, about 10 cm from the crest of the neck.
While performing the comparative tuberculin test, the site for the injection of avian tuberculin should be about 10 cm from the crest of the neck, and the site for injection of the bovine tuberculin about 12.5 cm lower. In young animals in which there is not room to separate the sides sufficiently on one side of the neck, one injection should be made on each side of the neck at identical sites in the centre of the middle third of the neck.
Skin 5 cm around the planned injection site should be free of any lesions. Before administering the product, the injection site should be marked by clipping a small cross with arm length of 2-3 cm. Next, a fold of skin with the clipped hair should be taken between the forefinger and thumb and measured with a calliper with accuracy of 0.1 mm. Tuberculin dose should be injected in the manner ensuring intradermal depositing of tuberculin. The needle, bevel edge outwards, should be inserted obliquely and intradermally. A correct injection should be confirmed by palpating a pea-like swelling at the injection site.
Tuberculin testing results should be recorded 72 (± 4) hours after injection. The injection site should be inspected and the fold of skin should be measured again.
Interpretation of results
The interpretation of reactions to tuberculin administration in cattle should be based on clinical observations and differences in skin-fold thickness at the injection site.
Single tuberculin test – one-off intradermal injection of bovine tuberculin and reading out of result:

a) positive reaction (+): if clinical changes are observed, such as diffuse or extensive oedema, exudation, necrosis, pain or inflammation of lymphatic ducts or lymph nodes in this area, or if increase in skin fold thickness at the injection site is greater than 4.0 mm;
b) inconclusive reaction (+/-): if no clinical signs listed in item a) are observed, and if increase in skin fold thickness is greater than 2.0 mm but smaller than 4.0 mm;
c) negative reaction (-): if limited, hardened swelling with increased skin fold thickness of less than 2.0 mm is observed, with no clinical signs.

Comparative tuberculin test – single, intradermal injection of bovine tuberculin and single, intradermal injection of avian tuberculin performed at the same time, and reading out of results:

d) positive (+): positive reaction at the bovine site of injection which is more than 4.0 mm greater than the reaction at the avian site of injection, or presence of clinical signs;
e) inconclusive (+/-): positive or inconclusive reaction with increase in skin thickness at the bovine site of injection which is 1.0 to 4.0 mm greater than the reaction at the site of avian injection, and absence of clinical signs;
f) negative (-): negative reaction at the bovine site of injection or positive or inconclusive reaction at the bovine site of injection which is less than or equal to the reaction at the avian site of injection, with absence of clinical signs.

The official procedure for assessing tuberculin test results and treatment of animals is set out in the instruction of the Chief Veterinary Officer.
Contraindications None
Adverse reactions None confirmed.
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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).
Withdrawal period
Meat and offal - zero days.
Milk - zero hours.
Special precautions for storage
Keep out of the reach and sight of children. Store in a refrigerator (2 - 8°C). Protect from light. Do not freeze. Shelf life after first opening the immediate packaging: 24 hours. Do not use after the expiry date stated on the label.
Special warnings
Special warnings for each target species:
Do not use the product in animals less than 6 weeks of age. It is not recommended to perform another tuberculin test earlier than 42 days after the last administration of the product.
Do not use in the period spanning 2 weeks before parturition and 2 weeks post-partum. Do not use the product during treatment with corticosteroids.

Marketing authorisation holder
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BIOWET Biowet PUŁAWY

Bovituberculin

FOR DIAGNOSING TUBERCULOSIS IN CATTLE

Solution for injection for cattle

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, thoroughly wash off the affected area with clean water. In case of accidental self-injection, seek medical assistance immediately and show the package leaflet or the label to the physician.
Pregnancy and lactation:
No data is available to state that the product has any adverse effect on pregnancy and lactation.
Due to increased risk of falsely negative results, tuberculin tests should not be performed in the period between 2 weeks before and 2 weeks after parturition.
Interaction with other medicinal products and other forms of interaction:
Simultaneous administration of corticosteroids or other immunosuppressants may weaken reaction to tuberculin and lead to emergence of falsely negative results.
Overdose (symptoms, emergency procedures, antidotes) if necessary:
The only effect of multiple administration of the product is decreased animal reactivity to subsequent tuberculin doses. This poses no threat to the life or health of animals.
Incompatibilities:
In the absence of incompatibility studies, this veterinary medicinal product should 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 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 any information on this veterinary medicinal product, please contact the marketing authorisation holder.

Package size 6 ml vial, containing 25 doses. Cardboard box containing 1 or 5 vials (1 x 25 doses, 5 x 25 doses).

Shelf life 2 years

For animal treatment only. To be supplied only on veterinary prescription. To be administered under veterinary supervision.

Marketing Authorisation 2628/17

CPLW 2017-02-27

Marketing authorisation holder
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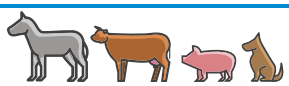
Biowet PUŁAWY

Calcii borogluconas 25% inj.

CALCIUM-BASED PRODUCT FOR INJECTION

Solution for injections in calcium deficiencies
Calcium gluconate 216,6 mg/ml



Active substance and excipient content 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 coagulation.

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

Power boost from Puławy

Calcii borogluconas 25% inj.

- Absorbs quickly
- Effectively replenishes calcium deficiency
- Competitive price
- Douche bag for 20 bottles

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 http://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:

- Acute hypocalcaemia – 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.

Marketing authorisation holder
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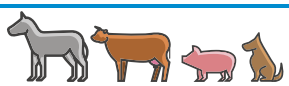
Biowet PUŁAWY

Calcii borogluconas 25% inj.

CALCIUM-BASED PRODUCT FOR INJECTION

Solution for injections in calcium deficiencies
Calcium gluconate 216,6 mg/ml



Withdrawal period
Horse, cattle, swine:
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.
Special precautions for persons administering the medicinal 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 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.
Overdose (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. Long-lasting 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.

Available containers 250 ml.

Shelf life 2 years
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Subject to medical prescription – prescription drug. To be administered under veterinary supervision. For animal treatment only.
Marketing authorisation 1170/01
2015-11-17 SPC

Marketing authorisation holder
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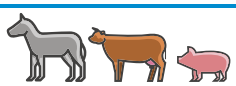
e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Calciglu c®

FOR TREATING CALCIUM AND MAGNESIUM DEFICIENCIES

Solution for injection, supplementing calcium and magnesium deficiencies for horses, cattle and swine



Active substance and excipient content **1 ml contains:**

Active substances:

Magnesium gluconate	60 mg/ml
Calcium gluconate	60 mg/ml
Magnesium chloride hexahydrate	30 mg/ml
Calcium chloride hexahydrate	27 mg/ml

Excipient:

Phenol	2.6 mg

Therapeutic indications

Horses: laminitis, urticaria.
Cattle: post-calving paralysis in cows, calcium and magnesium disorders such as Downer cow syndrome, hypocalcaemias and subclinical hypomagnesaemias, acute hypomagnesaemic tetanies.
Swine: post-farrowing hypocalcaemia in sows, rickets.

Liaison without a risk

Calciglu c®

- Magnesium enhances calcium intake
- Contains safe and verified magnesium and calcium doses
- Effective treatment of postpartum paralysis
- Douche bag for 20 bottles

Posology per each species, route and method of administration

Route of administration: intravenously.
horses, cattle – 0.5-1.0 ml/kg b.w.
swine – 2.0-5.0 ml/kg b.w.

Recommendations for proper administration

Inject slowly 25 – 50 ml/min.

Contraindications

Do not use in hyperparathyroidism and heavy renal insufficiency.
Do not use in hypermagnesaemia by impaired cardiac conductivity.
Do not use in the case of previous treatment with cardiac glycosides.

Adverse reactions

Unusually, in the case of high doses and in animals with bad general condition, it may cause hypercalcaemia in intravenous infusions. Bradycardia occurs at first, then the strength of the contraction is bigger and the heart rate increases with AV nodal *reentrant tachycardia* and extra systoles. Acute myocardial hypoxaemia occurs, then muscle tremor, anxiety, sweating and decreased arterial blood pressure leading to a collapse.
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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Withdrawal period

Horses, cattle, swine: Edible tissues – zero days
Cattle: Milk – zero hours.

Marketing authorisation holder
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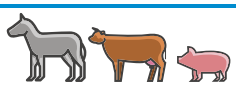
Biowet PUŁAWY

Solution for injection, supplementing calcium and magnesium deficiencies for horses, cattle and swine



Special precautions for storage

Keep out of the sight and reach of children.
Store at a temperature below +25°C. Protect from light. 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 warnings per each target species:
In the case of high doses in intravenous infusions particularly in animals with bad general condition it may cause hypercalcaemia.
Special precautions for use in animals:
In order to avoid administration of too high dose, the bodyweight of an animal has to be determined with the highest possible accuracy. In order to identify the symptoms of over-dosage at a proper time, the heartbeat should be monitored during the infusion.
The preparation needs to be heated to the body temperature and injected slowly in the amount of 25-50 ml/min.
Special precautions to be taken by the persons administering the veterinary medicinal product to animals:
In the case of accidental self-injection, immediately seek medical advice and show the package leaflet or the label to the physician.
Pregnancy: No contraindications.
Lactation: No contraindications.
Interactions with other medicinal products and other forms of interaction:
Cardiac glycosides intensify the cardiotoxic effect of calcium ions. Beta-adrenomimetics and methylxanthines intensify 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 absorption of tetracyclines and fluorine compounds (a three-hour interval is necessary between administration of these drugs and calcium compounds). Vitamin D, parathormone and acidic pH of food increase absorption of calcium whereas calcitonin, glycocorticosteroids, excessive amounts of lipids, alkaline reaction of food, phytates (e.g. in cereals), oxalates (e.g. in spinach, rhubarb) and phosphates (milk and dairy products) reduce absorption of calcium.
High doses of calcium administered in combination with cardiac glycosides (strophanthin derivatives and digoxins) intensify their effect and may lead to cardiac arrhythmias.
Thiazide diuretics increase resorption of calcium and pose a risk of hypercalcaemia.
High doses of calcium in combination with vitamin D may weaken the effect of verapamil and other calcium channel blockers.
Overdose (symptoms, procedures concerning immediate help and antidotes):
Overdose leads to hypercalcemia and hypermagnesemia, as well as to increased urinary calcium and magnesium excretion. Symptoms of hypercalcaemia and/or hypermagnesaemia may include: nausea, vomiting, increased thirst, polyuria, dehydration and constipation. Long-lasting overdose leading to hypercalcaemia and/or hypermagnesaemia 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.
Abnormal heart rate is a sign of overdose. In that case, abandon administration of the product.
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.

For animal treatment only. Subject to medical prescription – prescription drug.

Shelf life 2 years

Other information

Available containers 250 ml
Marketing authorisation 790/99
SPC 2016-04-20

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
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Calemfos

REPLENISHES CALCIUM, MAGNESIUM AND PHOSPHORUS STORES

Liquid calcium supplement for dairy cows

Ingredients:
Calcium carbonate – 27.8%
Propylene glycol – 9.3 %
Calcium phosphate dihydrate – 8.8 %
Magnesium chloride hexahydrate – 3.1 %
Feed additives
Carboxymethyl cellulose – (E 466) – 6000 mg/l
Niacinamide (3a315) – 122 mg/l
Water content: 50.4 %

Analytical constituents:	Per 1 kg	Per package (595 g)
Calcium content	131.0 g	78.0 g
Phosphorus content	15.8 g	9.4 g
Magnesium content	3.7 g	2.2 g

Treatment of Ca, Mg and P deficiency in the perinatal period

Calemfos

- Source of calcium, magnesium and phosphorus
- Replenishes energy shortages owing to glycol content
- Easy route of administration

Characteristics and indications
Calemfos is used in times of increased calcium and phosphorus demand during the periparturient period. Calemfos replenishes calcium and phosphorus stores depleted primarily by sudden loss of body fluids upon the start of lactation. Magnesium increases the efficiency of calcium utilization and glycol balances energy deficiencies.

Posology and method of administration:
Shake bottle energetically to mix its content thoroughly before use.
Calemfos dosage regimen:
1 bottle – 12 hours before labour
1 bottle – 6-12 hours after labour
1 bottle – 24 hours after labour
It is recommended to seek animal nutrition expert's opinion before use.
During administration exercise caution to prevent the animal from choking.

Storage
Store at a temperature below 25°C in a dark and dry place, in original, tightly closed containers.

Shelf life: 1 year.

Quantity: 595 g

Veterinary approval number Biowet Puławy Ltd., αPL0614003p
2017-10-18

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
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Biowet PUŁAWY

Calem® plus

REPLENISHES CALCIUM
AND MAGNESIUM STORES

Liquid calcium-based formula with magnesium for cows
Dietetic feeding stuff for dairy cows

Ingredients:
Vegetable oil – 28%
Calcium chloride – 25%
Magnesium citrate – 1.14%
Glucose – 0.65%
Technological additive emulsifier:
Polyoxyethylene sorbitan monooleate (E433) 5.62 mL/L
Water content: 46%

	In 1L (1000 mL)	In one package (445 mL)
Calcium content	112 g	50 g
Magnesium content	2.26 g	1 g

Absolutely essential (support) in the perinatal period

Calem plus

- Suplements calcium and magnesium deficiencies
- Easily absorbed and maintained high blood level
- Causes no irritation of forestomach mucosa due to vegetable oil content

Properties and indications:
Calem plus is used in the period of increased calcium demand during the perinatal period. Calem plus supplements calcium deficiency caused primarily by sudden loss of bodily fluids upon the start of lactation.
Directions for use:
Shake bottle content energetically to mix it thoroughly before use. Apply upon observing first signs of labour and continue for 2 days after labour is finished.
Dosage regimen:
1 bottle – 12 hours before labour
1 bottle – 6-12 hours after labour
1 bottle – 24 hours after labour
It is advisable to seek animal nutrition expert's opinion before use. During administration, exercise caution to prevent the animal from choking.
Storage:
Store at a temperature below +25°C, in a dark and dry place, in original, tightly closed containers.
Shelf life 1 year.
Volume 445 ml
Veterinary approval number Biowet Puławy Ltd., αPL0614003p
Date of the leaflet - 09.11.2015 r.

Marketing authorisation holder
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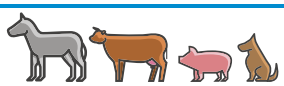
Biowet PUŁAWY

Calmagluc®

FOR TREATING CALCIUM, MAGNESIUM, PHOSPHORUS AND GLUCOSE DEFICIENCY

Solution for injections for cattle, horses, swine and dogs



Active substances and excipients content 1 ml contains:

Active substances:

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

Excipient:

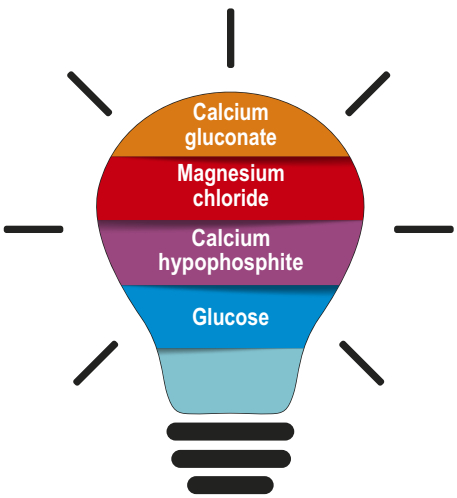
Phenol	2.6 mg

Therapeutic indications

Solution for injections indicated for use in horses, cattle, swine and dogs during calcium and magnesium deficiency. The product is used for treating clinical and subclinical hypocalcemia, hypomagnesemia and hypoglycemia, e.g. parturient paresis in cows, eclampsia in lactating dogs, postparturient hypocalcemia in sows.

Calmagluc is also applied while treating various allergies (urticaria in particular), as well as sub-acute and chronic calcium and magnesium disorders, such as Downer cow syndrome, and primarily subclinical hypomagnesemias. The product has been used for treatment of diseases emerging as a result of calcium and phosphate metabolic disturbances, such as rickets, osteomalacia and osteodystrophy. Further, it is administered while treating diseases with accompanying enhanced neuromuscular excitability, such as hypomagnesemic tetany in cattle, tetanus, tying-up in horses, as well as inflammations and poisonings with signs of increased vessel permeability, e.g. cerebral and pulmonary oedema, oedema disease in piglets, laminitis in horses (as an adjuvant).

Optimum level of Ca, Mg, P and glucose



Calmagluc

- Calcium is derived from compounds that gradually become ionized, which ensures longer maintenance of increased calcium concentration in body fluids
- Calcium gluconate metabolism is slow, whereas calcium hypophosphite – which is also a source of phosphorus – is moderately dissociated
- Magnesium chloride gets almost fully dissociated and exerts immediate biological action, whereas glucose eliminates moderate hypoglycemia that often co-occurs with metabolic disorders

Posology per each species, routes and methods of administration

To be administered intravenously or intramuscularly. In horses and dogs, only intravenous administration is allowed.

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

- Chronic and sub-acute, both primary and secondary metabolism of macro elements, as well as morphology disorders resulting from calcium and phosphate metabolic disturbances, such as rickets, osteomalacia and osteodystrophy – administer doses of **5 ml/kg b.w. intravenously or intramuscularly, once a day for 3-7 days**. Extend treatment by using compound feeds with minerals.
- Acute disturbances with advanced hypocalcemia and hypomagnesemia, such as parturient paresis and hypomagnesemic tetany – administer doses of **1.0-1.5 ml/kg b.w. intravenously or intramuscularly, single administration, double administration, and in special cases triple administration, in 12-hour intervals.**
- Diseases not directly related to calcium and phosphate metabolic disturbances and as an adjuvant in inflammations, allergies and poisonings (urticaria, laminitis, edemas, enhanced neuromuscular excitability) – administer doses of **0.3-0.5 ml/kg b.w., every second day for 6-14 days.**

Recommendations for proper administration

When administered intravenously, heat to body temperature and inject slowly (25-50 ml/min for large animals, 15-30 ml/min for small animals). For example: 500 ml of the product in large animals should be administered for no less than 5-10 minutes.

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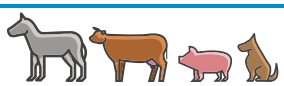
Biowet PUŁAWY

Calmagluc®

CALCIUM PREPARATION WITH PHOSPHORUS, MAGNESIUM AND GLUCOSE, FOR INJECTIONS FOR CATTLE, HORSES, SWINE AND DOGS

Solution for injections for cattle, horses, swine and dogs



Contraindications
Hyperparathyroidism and renal failure. Hypercalcemia, acidosis. Hypermagnesemia, Myastenia gravis in dogs, slow conduction in cardiac muscle. Previous use of cardiac glycosides, beta adrenomimetic drugs and caffeine.

Adverse reactions
Calcium gluconate, magnesium chloride, calcium hypophosphite and glucose have a wide margin of safety, and any toxic effect results from administration of doses in excess of multiple therapeutic doses. In exceptional cases, after administering high doses of the product in animals with poor general health, hypercalcemia may occur during intravenous injections. Bradycardia develops; strength of single contraction increases, just as the contraction frequency with AV nodal *reentrant tachycardia* and additional contractions. Acute myocardial hypoxia occurs, followed by muscle tremor, anxiety, sweating, decreased blood pressure, leading to collapse. In order to promptly recognize overdose signs, heart rate should be monitored during infusion.

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

Withdrawal period
Horses, cattle, pigs: Edible tissues – zero days.
Cattle: Milk – zero hours. Dogs: 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. The durability period after the first opening of the immediate container: 28 days. Do not use this veterinary medicinal product after the expiry date stated on the label.

Special warnings
Special warnings for each target species: Use caution with animals with poor general health in which excessive drug doses may cause myocardial hypoxia and decreased blood pressure leading to collapse.

Special precautions for use in animals:

When administered intravenously, heat to body temperature and inject slowly (25-50 ml/min for large animals, 15-30 ml/min for small animals).

For example: 500 ml of the product in large animals should be administered for no less than 5-10 minutes. In order to avoid overdose, determine animal body weight as precisely as possible. In order to ensure timely recognition of overdose signs, monitor heart rate during the infusion.

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

Do not eat, drink or smoke while handling the veterinary medicinal product. Use caution to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package insert to the physician. Wash hands after use.

Pregnancy: Can be used during pregnancy.

Lactation: Can be used during lactation.

Interaction with other medicinal products and other forms of interaction:

Cardiac glycosides intensify cardiotoxicity of calcium ions. Beta-adrenomimetic drugs and methylxanthines intensify cardiac effect of calcium ions. Simultaneous oral administration of tetracycline antibiotics enhances binding of calcium ions to proteins. It is not recommended to mix Calmagluc with thiazide diuretics, glucocorticoids, bile acid sequestrants, oxalic acid and phytic acid, laxatives, e.g. paraffin oil. Due to magnesium ion content, Calmagluc may display antagonistic activity to other calcium preparations. Magnesium decreases gastrointestinal absorption of theophylline, tetracycline antibiotics, iron preparations, fluorine compounds, oral anticoagulants and warfarin derivatives. Diuretics, cisplatin, cycloserine, mineralocorticoids increase urinary magnesium excretion. Aminoglycosides, muscle relaxants and colistin used simultaneously with magnesium preparations may cause muscle paralysis. As a result of urine alkalinization, renal excretion of quinidine is decreased, thus posing the risk of overdose.

Overdose (symptoms, procedures concerning immediate help and antidotes):

Overdose leads to hypercalcemia and hypermagnesemia, as well as to increased urinary calcium and magnesium excretion. Symptoms of hypercalcemia and hypermagnesemia may include: nausea, vomiting, excessive thirst, polyuria, dehydration and constipation. Long-lasting overdose leading to hypercalcemia and/or hypermagnesemia can cause vascular and organ calcification 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.

Abnormal heart rate is a sign of overdose. In that case, abandon administration of the product.

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.

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.

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

Shelf life 2 years

Available containers: 250 ml

Marketing authorisation 1317/02

SPC 2016-04-11

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Biowet PUŁAWY

Canifos

TABLETS IMPROVING DOG's GROWTH AND DEVELOPMENT

Supplementary feed for dogs

Ingredients
Dicalcium phosphate, wheat/potato starch, processed animal protein (PAP), brewer's yeast, pork gelatin, magnesium stearate.
Analytical constituents
Total protein 5.73%, crude fat less than 1%, crude fibre less than 1%, crude ash 73.25 %.
Characteristics and indications
Mineral macronutrients and trace elements are blended into a harmonious formula regulating your dog growth and development. It provides nutrients ensuring proper bone development and strength. Canifos is recommended for all dogs, especially when their food contains insufficient amount of minerals and vitamins.

May your dog grow rich in minerals

Canifos

- provides minerals and vitamins for a healthy diet
- supplies nutrients determining normal bone structure and strength
- supports body development
- tasty tablets attract the dog with their smell

Application and dosage:
Small breed dogs – one tablet twice a day
Medium breed dogs – one and a half tablets twice a day
Large breed dogs – two tablets twice a day
CAUTION: This product contains animal-derived protein which is prohibited in ruminant feed.
Nutrition facts for one tablet:

Calcium	– 630 mg	Zinc	– 275 µg
Phosphorus	– 400 mg	Manganese	– 23 µg
Magnesium	– 1.2 mg	Copper	– 18 µg
Sodium	– 0.9 mg	Protein	– 200 mg
Potassium	– 1.4 mg	Fat	– 40 mg
Iron	– 36 µg		

Natural vitamins, mainly of the B complex
Storage:
Store in a dry cool place.
Shelf life: 18 months
Canifos contains no preservatives.
Net weight: 2.5 g. Pack size: 75 tablets
For animal treatment only
Veterinary approval number **06148301**
Date of development of the leaflet - 2019-02-26

Marketing authorisation holder
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Biowet PUŁAWY

Canifos betaglukan

Supplementary feed for dogs

Ingredients
Dicalcium phosphate, magnesium stearate, beta-1,3/1,6-D-glucan (derived from *Saccharomyces cerevisiae*), brewer's yeast, processed animal protein (PAP), wheat/potato starch, pork gelatin.
Analytical constituents: total protein 9.79 %, crude fat 1.39 %, crude fibre less than 1 %, crude ash 67.87 %.

Characteristics and indications
Canifos betaglukan contains beta-1,3/1,6-D-glucan, purified natural polysaccharide isolated from cell walls of *Saccharomyces cerevisiae*. Beta-glucan stimulates the immune system by activating macrophages, lymphocytes and neutrophils. Macrophages play the key role in anti-infectious immunity, removing abnormal or dead cells and foreign substances from the body. Beta-glucan reinforces the effects of other medicinal products (antibiotics, antifungal and anti-parasitic agents), accelerates tissue regeneration, it has anticancer and anti-oxidative effects, it neutralizes free radicals. Mineral substances and naturally obtained trace elements contained in Canifos betaglukan are blended into a harmonious formula regulating your dog growth and development.

Let each dog acquire immunity

Canifos betaglukan

- stimulates the immune system
- improves vitality
- supports healthy development of the body

Canifos betaglukan is recommended in dogs:
- as a supplement during treatment of bacterial, viral, fungal and parasitic infections;
- as a supplement during treatment of cancer diseases;
- during the recovery period;
- during the reproduction period;
- in stressful situations (exhibitions, travel, change of environment);
- as a preventive measure.

Application and dosage:
Small breed dogs – one tablet twice a day.
Medium breed dogs – one and a half tablets twice a day.
Large breed dogs – two tablets twice a day
CAUTION: This product contains animal-derived protein which is prohibited in ruminant feed.

Additional information:
Nutrition facts for one tablet:

Calcium	– 520 mg	Iron	– 2,2 mg
Phosphorus	– 358 mg	Zinc	– 238 µg
Magnesium	– 2,4 mg	Manganese	– 25 µg
Beta-glucan	– 20 mg	Copper	– 24 µg
Sodium	– 3,8 mg	Protein	– 230 mg
Potassium	– 3,6 mg	Fat	– 35 mg

Natural vitamins, mainly of the B complex
Storage: Store at room temperature in a dry place.
Shelf life: 18 months
Canifos betaglukan contains no preservatives.
Net weight: 2.5 g. Pack size: 75 tablets
For animal treatment only
Veterinary approval number **06148301**
Date of development of the leaflet - 2019-03-07

Marketing authorisation holder
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Canifos deo

TABLETS RESTRICTING DEVELOPMENT OF UNPLEASANT ODOURS

Supplementary feed for dogs

Ingredients
dicalcium phosphate, magnesium stearate, chlorophyll, brewer's yeast, processed animal protein (PAP), wheat/potato starch, pork gelatin.
Additives
Colourant 2 a – copper complex of chlorophyllin (E 141) – 4 800 mg/kg
Analytical constituents
Total protein 5.04±0.27%, crude fat less than 1%, crude fibre less than 1%, crude ash 72.05±8.93%.
Characteristics and indications
Canifos Deo is recommended to reduce unpleasant odours of the breath, skin or dog droppings. Copper complexes of chlorophyllin contained in the product are intended to reduce body odours, including odours related to uncontrolled excretion of urine and feaces, and reduce female scent produced during the heat cycle. **Canifos Deo** is especially recommended to regulate the digestive processes during which unpleasantly smelling odours are emitted. They are neutralized by chlorophyll contained in the product. **Canifos Deo** purifies body from harmful metabolites, enriches the diet with natural vitamins of the B complex.

Fewer unpleasant odours

Canifos deo

- prevents development of unpleasant odours of breath, skin and faeces
- supports digestive processes
- restricts development of odour produced by a female dog during oestrus

Application and dosage
Administer tablets directly into the mouth or in other feed.
Small breed dogs – one tablet twice a day
Medium breed dogs – one and a half tablets twice a day
Large breed dogs – two tablets twice a day
CAUTION: This product contains animal-derived protein which is prohibited in ruminant feed.
Net weight 2.5 g. Pack size: 75 tablets.
Storage
Store at room temperature in a dry place.
Shelf life: 18 months
Veterinary approval number: 06148301
Date of development of the leaflet-08.11.2017

Marketing authorisation holder
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Biowet PUŁAWY

Canifos junior

TABLETS SUPPORTING NORMAL BONE GROWTH

Supplementary feed for growing dogs

Ingredients
Calcium lactate, dicalcium phosphate, magnesium stearate, beta-1,3/1,6-D-glucan (derived from *Saccharomyces cerevisiae*), magnesium oxide, brewer's yeast, processed animal protein (PAP), wheat/potato starch, pork gelatin.
Analytical constituents: total protein 10.31%, crude fat 1.23%, crude fibre less than 1%, crude ash 43.26%.
Characteristics and indications
Canifos junior was designed for young growing dogs, and for pregnant and lactating female dogs. It offers proper calcium to phosphorus ratio, as well as macro and microelements essential for proper bone growth. In addition, Canifos junior contains beta-1,3/1,6-D-glucan, purified natural polysaccharide isolated from cell walls of *Saccharomyces cerevisiae*, stimulating the body's natural immune system.
Directions for use
1 tablet per 5 kg of body weight/day.
CAUTION*: This product contains animal-derived protein which is prohibited in ruminant feed.*

Let every dog have strong bones

Canifos junior

- prevents deficits which are a cause of e.g. limb rickets
- supplies adequately balanced calcium and phosphorus, as well as macro- and microelements, necessary for normal growth of bones
- ß-1,3/1,6-D-glucan stimulates defence mechanisms of the body

Additional information:
Nutrition facts for one tablet:

Calcium	– 375 mg	Iron	– 1.7 mg
Phosphorus	– 126 mg	Zinc	– 100 µg
Magnesium	– 7,8 mg	Manganese	– 25 µg
Beta-glucan	– 20 mg	Copper	– 11 µg
Sodium	– 3.5 mg	Protein	– 237 mg
Potassium	– 3.4 mg	Fat	– 104 mg

Natural vitamins, mainly of the B complex
Storage
Store in a dry cool place.
Shelf life 18 months
Canifos junior contains no preservatives.
Net weight: 2.5 g. Pack size: 75 tablets.
For animal treatment only
Veterinary approval number **06148301**
Date of the leaflet - 02.11.2017

Marketing authorisation holder
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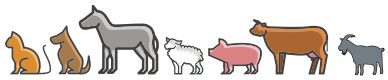
e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Coffenal

Solution for injections
Caffeine 80mg/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.
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.
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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).
Withdrawal period
Meat and offal: 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.).
Pregnancy: 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.
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.
Shelf life 2 years
For animal treatment only. Subject to medical prescription – prescription drug. To be administered under veterinary supervision.
Available pack: amber glass bottles containing 50 ml of the product.
2016-03-31 SPC. Marketing authorisation: 23/94.

Marketing authorisation holder
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Deodent

LOTION AGAINST ORAL ODOURS

Liquid formula for eliminating bad breath in cats and dogs

Ingredients
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.

To breath freely

Deodent

- neutralizes offensive odour from the mouth
- prevents development of caries
- strengthens the tooth enamel
- dissolves mineral sediment

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.
Date of the leaflet-25.10.2013 r.

Marketing authorisation holder
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Depogeston

PRODUCT PREVENTING OESTRUS
IN FEMALE DOGS AND CATS

Suspension for injection for dogs and cats
Medroxyprogesterone acetate 50 mg/ml

Active substance and excipients content
Active substance:
Medroxyprogesterone acetate – 50 mg/ml
Excipients:
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.

Prevention of oestrus in female dogs and cats

Medroxyprogesterone acetate

is an analogue of natural progesterone. It is slowly released from the injection site, ensuring constant level in blood. As a result, secretion of gonadotropic hormones is inhibited, which in turn causes inhibition of follicle development and regression of oestrus symptoms.

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 http://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:
bitches: 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.

Marketing authorisation holder
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BIOWET Biowet PUŁAWY

Depogeston

PRODUCT PREVENTING OESTRUS IN FEMALE DOGS AND CATS

Suspension for injection for dogs and cats

Medroxyprogesterone acetate 50 mg/ml

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: 28 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.
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 6 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

To be administered under veterinary supervision.

Marketing authorisation 978/00
2018-06-04 SPC

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
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Elisol

Supplementary compound feed for pigeons

Ingredients

Sodium chloride (NaCl)	–	4070 mg/l
Calcium chloride hexahydrate ($CaCl_2 \cdot 6H_2O$)	–	550 mg/l
Magnesium chloride hexahydrate ($MgCl_2 \cdot 6H_2O$)	–	50 mg/l
Feed additives:		
Potassium citrate monohydrate ($C_6H_5O_7K_3 \cdot H_2O$) [preservative 1a E332] – in the mixture the source of potassium ions K^+	–	18 250 mg/l
Sodium citrate dihydrate ($C_6H_5O_7Na_3 \cdot 2H_2O$) [preservative 1 a E 331] – in the mixture the source of sodium ions Na^+	–	1 910 mg/l
Iron chloride hexahydrate ($FeCl_3 \cdot 6H_2O$) [trace element 3 b E 1]	–	1 160 mg/l
Citric acid monohydrate ($C_6H_8O_7 \cdot H_2O$) [preservative 1 a E 330] – in the mixture pH stabiliser	–	190 mg/l
Zinc chloride ($ZnCl_2$) [trace element 3 b E 6]	–	177 mg/l

Analytical constituents: total protein below 5%, crude fat below 1%, crude fibre below 1%, crude ash below 2%, water 98%.

Electrolytes for pigeons

Elisol recomended:

- before and after flights
- in dehydration states
- in macro- and microelement deficits
- in stressful situations

Indications:
Elisol is a multi-electrolyte solution used in dehydration, after physical effort and in stressful situations such as transport, exhibitions and feebleness after flights. Elisol strengthens the pigeon's body through supplementation of deficient micro- and macroelements.
Flight pigeons should receive Elisol before the flight and after the contest.

Posology:
Elisol should be administered in drinking water 10 ml per 1l of water which constitutes a dose for 20 pigeons. The vessels should be cleaned.
Water used for dilutions should be clean, preferably boiled.
Elisol should be administered twice a week.

Storage:
Store at room temperature. Once opened, the durability of the product is max. 4 weeks. Protect from light.

Shelf life
18 months

Available pack size
100 ml

For animal treatment only.
Veterinary identification number: αPL0614003p
Date of development of the leaflet - 09.11.2015 r.

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Biowet PUŁAWY

Enflocyna®

Solution for injection for cattle and pigs
Enrofloxacin 100mg/ml

Active substance and excipients content
Active substance:
Enrofloxacin – 100 mg/ml
Excipient:
Benzyl alcohol (E-1519) – 15.7 mg/ml
Therapeutic indications
Cattle
Treatment of respiratory tract infections caused by strains of *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma* spp. susceptible to enrofloxacin.
Treatment of gastrointestinal tract infections caused by strains of *Escherichia coli* susceptible to enrofloxacin.
Treatment of septicaemia caused by strains of *Escherichia coli* susceptible to enrofloxacin.
Treatment of acute mycoplasma arthritis caused by strains of *Mycoplasma bovis* susceptible to enrofloxacin in cattle aged less than 2 years.
Pigs
Treatment of respiratory tract infections caused by strains of *Pasteurella multocida, Mycoplasma* spp. and *Actinobacillus pleuropneumoniae* susceptible to enrofloxacin.
Treatment of urinary tract infections caused by strains of *Escherichia coli* susceptible to enrofloxacin.
Treatment of Postpartum Dysgalactia Syndrome – PDS (Metritis Mastitis Agalactia MMA) caused by strains of *Escherichia coli* and *Klebsiella* spp. susceptible to enrofloxacin.
Treatment of gastrointestinal tract infections caused by strains of *Escherichia coli* susceptible to enrofloxacin.
Treatment of septicaemia caused by strains of *Escherichia coli* susceptible to enrofloxacin.

Fast and effective action

Enflocyna

- has broad-spectrum activity
- is rapidly absorbed
- is effective in the treatment of general diseases and local bacterial infections
- withdrawal period for milk – 4 days

Amount to be administered per species, method and route of administration
Product for subcutaneous or intramuscular use. Subsequent product doses to be administered at different injection sites.
Cattle
5 mg of enrofloxacin per kg of body weight, which corresponds to 1 ml per 20 kg of body weight, injected subcutaneously once a day for 3–5 days.
Acute mycoplasma arthritis caused by *Mycoplasma bovis* susceptible to enrofloxacin in calves aged less than 2 years: 5 mg of enrofloxacin per kg of body weight, which corresponds to 1 ml per 20 kg of body weight, injected subcutaneously once a day for 5 days. In case of subcutaneous administration, do not inject more than 5 ml of the product per site.
Pigs
2.5 mg of enrofloxacin per kg of body weight, which corresponds to 0.5 ml per 20 kg of body weight, injected intramuscularly once a day for 3 days.
Gastrointestinal tract infection or septicaemia caused by *Escherichia coli*: 5 mg of enrofloxacin per kg of body weight, which corresponds to 1 ml per 20 kg of body weight, injected intramuscularly once a day for 3 days.
Inject the product in the neck, near the base of the ear.
Do not exceed 3 ml per site.
Instructions for use
In order to ensure proper amounts to be administered, determine body weight as precisely as possible, to avoid dose underestimation.
Contraindications
Do not use the product as a preventive measure. Do not use in case of known bacterial resistance/cross-resistance to

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Biowet PUŁAWY

Solution for injection for cattle and pigs

Enrofloxacin 100mg/ml

fluoroquinolones or quinolones. Do not use in case of hypersensitivity to the active substance or any excipient. Do not use in growing horses due to risk of joint cartilage damage.

Adverse reactions

Reported very rarely. Long-term use of high product doses in growing animals may lead to developmental changes in cartilage and transitory alimentary tract and nervous system disorders.

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

Withdrawal period

Cattle: Edible tissues: 12 days.
Milk: 4 days.
Pigs: Edible tissues: 13 days.

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. Expiry date refers to the last day of a given month.

Special warnings

Special precautions for use in animals:

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.

Principles of prudent use:

If possible, fluoroquinolone use should be based on results of antibiotic resistance test.

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 flouroquinolones and decreased efficacy of treatment using fluoroquionolones 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, immediately seek doctor's assistance and present the doctor with the information leaflet or package. In case of contact with skin, mucous membranes – immediately flush affected sites 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 breastfeeding.

Interaction with other medicinal products and other forms of interaction:

Do not use together with macrolide, tetracycline antibiotics and theophylline.

Overdose (symptoms, emergency procedures, antidotes):

Enrofloxacin displays low toxicity after single-dose administration, and low acute toxicity. LD_{50} is about 4000-5000 mg/kg of body weight after *per os* administration in rats and mice, whereas in rabbits which are more susceptible – 500-800 mg/kg of body weight.

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

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

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

Shelf life 2 years

For animal treatment only.

Subject to medical prescription – prescription drug.

To be administered only by a veterinary surgeon.

Marketing authorisation 715/992015-04-22 SPC

Marketing authorisation holder
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Biowet PUŁAWY

Enflocyna® Sol

ENROFLOXACIN ORAL SOLUTION

Oral solution for cattle, swine, dogs, hens, turkeys and pigeons.
Enrofloxacin 50mg/ml

Active substance and excipient content:
Active substance: Enrofloxacin – 50 mg/ml
Excipient: benzyl alcohol

Therapeuthic indications
Enflocyna Sol is effective in the treatment of general and local diseases induced by sensitive microorganisms, especially in bacterial infections of the respiratory system and the urogenital system as well as in bacterial skin diseases, wound infections and secondary infections in viral diseases. It has a wide spectrum of action embracing gram-positive bacteria (especially *Staphylococcus spp., Streptococcus spp.*), gram-negative bacteria (*E. coli, Salmonella spp., Pasteurella spp., Klebsiella spp., Pseudomonas spp.*) and mycoplasmas.
Efficiency of enrofloxacin was particularly confirmed in the treatment of the following diseases in target species:

Hens and turkeys: Mycoplasmosis induced by *M.gallisepticum, M.synovie, M.meleagridis, M.iowae,*
Colibacteriosis,
Infectious rhinitis of birds,
Salmonellosis,
Pasteurellosis,
Staphylococcosis,
Erysipelothrix rhusiopathiae in turkeys,
Campylobacteriosis,
Viral infections in the course of viral diseases.
Cattle: infections of the respiratory tract and the urinary system, diarrhoeas
Swine: diarrhoeas, enterotoxaemias induced by *E.coli* and *Salmonella spp.*, infections of the respiratory tract and the urinary system, MMA syndrome
Dogs: infections of the respiratory tract and the urinary system, diarrhoeas

Fighting bacterial infections

Enflocyna Sol

- has broad-spectrum activity
- is effective in the treatment of general diseases and local bacterial infections
- low toxicity

Pigeons: salmonellosis, mycoplasmosis, general and local infections induced by microorganisms sensitive to enrofloxacin

Contrindications
Do not use in lactation in cows whose milk is intended for human consumption. Do not use in hens laying eggs for consumption. Do not use in pregnant animals and in lactation. Do not use in the case of diagnosed resistance to quinolones. Do not use in dogs of small breeds aged up to eight months and in dogs of big breeds aged up to one year and in dogs of very big breeds aged even up to 1.5 years.

Adverse effects
They occur very seldom. After long-lasting use of high doses, developmental changes in articular cartilages in growing animals and temporary functional disorders of the alimentary tract and the nervous system may occur.
A proper veterinary surgeon, the Marketing Authorisation Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products should be notified of any occurrence of adverse effects after administration of the product or observation of any alarming symptoms not listed in the leaflet (including symptoms in people as a result of contact with the drug). The notice form has to be downloaded from the website http://www.urpl.gov.pl (The Department of Veterinary Medicinal Products).

Posology and routes of administration
Enflocyna Sol is administered to animals after previous dissolution in drinking water, milk or milk substitutes.

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BIOWET Biowet PUŁAWY

Enflocyna® Sol

ENROFLOXACIN ORAL SOLUTION

Oral solution for cattle, swine, dogs, hens, turkeys and pigeons.
Enrofloxacin 50mg/ml

The bodyweight of an animal has to be determined accurately when determining the dose.
The general posology for Enflocyna Sol is as follows:
– Hens and turkeys – 0.20 ml/kg which corresponds to 100 ml/100 litres of drinking water, for three days, in salmonellosis – 5 days
– Cattle – 0.05-0.10 ml/kg b.w. for 3-5 days
– Swine – 0.05-0.10 ml/kg b.w. for 3-5 days
– Dogs – 0.05-0.10 ml/kg b.w. for 3-5 days
– Pigeons – 1.0-4.0 ml/litre of drinking water,
– salmonellosis: 4 ml/litre of water daily for 3 days or 2 ml/litre for 7-10 days
– mycoplasmosis, infectious rhinitis in pigeons: 2 ml/litre of water for 4-7 days
– other bacterial infections: 1 ml/litre of water daily for 3-4 days/

Recommendations for proper administration
The prepared solution of Enflocyna Sol should be used within 24 hours.

Waiting period
Dogs – not applicable.
Meat and offal of cattle and swine – 10 days.
Meat and offal of hens – 7 days.
Meat and offal of turkeys – 13 days.
Do not use in hens laying eggs for consumption.
Do not use in pigeons for consumption.
Do not use in lactation in cows whose milk is intended for human consumption.

Special precautions for storage and transport
Store at a temperature below +25°C. Protect from light. Do not freeze. Durability after the first opening of the direct package – 28 days. Durability after dilution with drinking water, milk or milk substitutes: – 24 hours. Keep out of the sight and reach of children.

Special warnings and precautions
The drug can only be used in bacterial infections induced by microorganisms whose sensitivity was confirmed by an antibiogram and in the case of resistance to other chemotherapeutics. The drug cannot be used for treatment of infections with smaller intensity (significance). The drug should not be used in the case of diagnosed resistance to quinolones (cross-resistance). In the case of contact of the product with the skin, mucous membranes – rinse the sites with water immediately. Store in a place secured against access by third parties. Do not use in pregnancy and lactation. Do not use in hens laying eggs for consumption. Do not use in combination with macrolide antibiotics, tetracyclines and theophylline and in pigeons with coccydiostats. Magnesium and aluminium compounds may reduce absorption of enrofloxacin from the alimentary tract. Unused veterinary medicinal product or its waste should be neutralised in accordance with appropriate regulations.

Shelf-life 2 years

Exclusively for animals. Prescription-only-medicine (POM). For use under the supervision of a veterinary surgeon

Packages Phials of 50 ml.
Marketing authorisation 716/99
SPC 2018-06-20

Marketing authorisation holder
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Biowet PUŁAWY

Gentamycyna
Biowet Puławy

PRODUCT USED IN THE TREATMENT OF BACTERIAL INFECTIONS

Solution for injection for dogs and cats
Gentamicin 50 mg/ml

Active substance content
Gentamicin (in the form of gentamicin sulphate) 50 mg/ml
Therapeutic indications
The product is used in dogs and cats:
– infections of the respiratory tract caused by *Staphylococcus sp., Pseudomonas aeruginosa, Klebsiella sp., Mycoplasma sp.,*
– infections of the urogenital tract 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.,
– in skin and ear infections caused by *Staphylococcus* sp., *Pseudomonas aeruginosa, Proteus* sp.,
– in joint infections caused by *Staphylococcus* sp., *Pseudomonas aeruginosa.*
Posology per target species, routes and methods of administration
Gentamicin is administered subcutaneously or intramuscularly in a dose of 0.8 ml/10 kg b.w. (which corresponds to 4 mg of gentamicin /kg b.w.)
– on the first day of treatment the drug is administered every 12 hours
– next days – once daily every 24 hours.
This antibiotic is generally administered within 4-5 days; in urinary infections 7-10 days. Alkalisation of urine increases the activity of the antibiotic.
Recommendations for proper administration None.
Withdrawal period Not applicable.
Contraindications
Pregnancy. Renal insufficiency. Allergy to aminoglycoside antibiotics. The drug should not be used in highly dehydrated animals.
Adverse reactions
Long-lasting administration or overdosing of gentamicin may lead to damage to kidneys or the organ of hearing. Intracanal administration may induce inflammation of the nerve roots of the medulla, fever and chronic pleocytosis. 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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).
Special precautions for storage
Keep out of the sight and reach of children. Store at a temperature below 25°C. Protect from light. Do not freeze. Use within 28 days after the first opening of the container. Do not use after the expiry date given on the label.
Special warnings
Special precautions for use in animals:
Young animals, in which the process of renal elimination of gentamicin is slower than in adult animals, are more susceptible to the toxic effect of the drug. Use half the recommended doses in animals aged up to two weeks. The product should be used on the basis of results of resistance tests for bacteria isolated from sick animals. If this is impossible, treatment should be performed on the basis of local epidemiological information concerning sensitivity of isolated bacteria. If the condition of an animal requires longer administration of the drug, monitoring the condition of the kidneys is recommended through concentrations control of urea and creatinine in the blood serum.
Special precautions for persons administering the medicinal veterinary product to animals:
The product may have a sensitising effect on the skin causing contact dermatitis. During administration of the drug, protective clothing should be worn and special caution should be exercised. On accidental contact with the drug, the solution should be washed from the skin or the mucous membranes immediately. In the case of a self-injection, a hypersensitivity reaction may occur. After accidental self-injection, immediately seek medical help and show the information leaflet or the package to the physician.
Pregnancy: Do not use throughout pregnancy.
Lactation: Due to the nephrotoxic effect, use carefully in lactation 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 displays cross-resistance with other amino glycosides. It has a synergic effect with β-lactam antibiotics (especially ampicillin and benzyl penicillin) on enterococci, staphylococci and streptococci. It also has a synergic effect with vancomycin and rifampicin on streptococci and staphylococci. Cephalosporins and some diuretics intensify nephrotoxicity and ototoxicity of the drug. Therefore, the drug cannot be administered in combination with cephalotin, cephaloridine, etacrynic acid, mannitol and furosemide. Its simultaneous use with vancomycin intensifies nephrotoxicity of both drugs. A combination with cisplatin reduces excretion of gentamicin thus posing a risk of nephrotoxicity and hypomagnaesemia. The preparation should not be mixed with solutions of penicillins with a wide spectrum because it may lead to inactivation of amino glycoside. The simultaneous use with amphotericin B, cyclosporine, cisplatin, methoxyflurane, acyclovir and non-steroid anti-inflammatory drugs may result in renal damage. Gentamicin administered in general anaesthesia in combination with cyclopropane may cause apnoea.
Overdose (symptoms, procedures concerning immediate help and antidotes): After gentamicin overdose, functional disorders of the kidneys, neuromuscular block, impaired hearing may occur. In such a case, the administration of the drug should be discontinued.
Pharmaceutical incompatibilities: Do not use with other antibiotics, strong diuretics and potentially nephrotoxic and ototoxic drugs.
Do not combine with anaesthetics or myorelaxants.
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 three years. The durability period after the first opening of the immediate container: 28 days.
Avaiable containers 50 ml
For animal treatment only. Subject to medical prescription – prescription drug. To be administered under veterinary supervision.
Marketin authorisation 281/96
2014-04-18 SPC

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Immunex complex

Immunity boosting capsules for pigeons

Supplementary fodder mixture for pigeons

Composition

Dicalcium phosphate, glucose, grape seed extract 95%, β-1,3/1,6-D-glucan (product obtained from yeast *Saccharomyces cerevisiae*), magnesium stearate

Excipients

Ascorbic acid (3a)	250 000 mg/kg
Vitamin E (3a700)	8 000 mg/kg
β -carotene (E160a)	16 000 mg/kg
Purple coneflower (2b)	50 000 mg/kg
Colloidal silica (E551b)	20 000 mg/kg

Analytical composition

crude fibre: below 1.00%, crude ash: 24.71 ± 3.06%, total protein: below 5.00%, total fat after hydrolysis: 1.61 ± 0.21%

Capsule composition

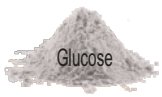
β-1,3/1,6-D-glucan	34 mg
β-carotene	16 mg
Vitamin E 50%	16 mg
Purple coneflower extract	50 mg
Grapefruit seed extract	170 mg
Ascorbic acid	250 mg
Dicalcium phosphate	234 mg
Glucose	190 mg
Magnesium stearate	20 mg
Colloidal silica	20 mg

Fundamental immunity

Immunex complex contains:

stimulates antibody production

has antiviral, antifungal, antiallergic and antineoplastic effect



Source of energy

Protects the cardiovascular system, inhibits formation of free radicals

improves immunity

facilitates wound healing, has antiinflammatory effect

Indications for use

The product is indicated for use in pigeons with reduced immunity resulting from infection, before competition flights, exhibitions, transport, during nestling rearing time, during convalescence after diseases.

Immunex complex is recommended in adjuvant therapy of viral and bacterial disease and in the vaccination period. It is particularly indicated for young pigeons and flying pigeons when they are required to be in top form.

Properties

Immunex complex contains **betaglucan** which stimulates production of antibodies, which induces improvement of immunity to infections. Betaglucan also accelerates regeneration of tissues, has antineoplastic properties and is an antioxidant. **Purple coneflower** has antiviral, antifungal, anti-allergic and antineoplastic properties. **The grape seed extract** protects the cardiovascular system, counteracts occurrence of free radicals and removes them from the body. **Ascorbic acid** (vitamin C) boosts the body's immunity. **Vitamin E** has an anti-inflammatory effect, accelerates wound healing, and prevents damage to the cell membrane induced by free radicals. It also protects against clot formation in blood vessels. **Glucose** is a basic energy source necessary for the proper function of the body.

Posology

In adjuvant therapy:

– during rearing time: 2 capsules/1kg of fodder for seven days,

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Immunex complex

Immunity boosting capsules for pigeons

Supplementary fodder mixture for pigeons

– in vaccination period: 2 capsules/1kg of fodder for 10 successive days before vaccination,
– during infection treatment: 2 capsules/1kg of fodder throughout antibiotic therapy and three days afterwards.
After the therapy, at least a two-week break is recommended before re-application.
In prophylaxis:
1 capsule/1 kg of fodder for 10 successive days.

Method of administration

Mix the content of the capsule in a small amount of oil or water with added honey, according to the user's preferences, before mixing with fodder. The product which is prepared in such a manner can be added to grain and mixed thoroughly. If diarrhoeas occur in the flock, oil is not recommended for use as a grain lubricant.

Additional information

Storage conditions

Store in a dry and cool place.

Pack size: 70 capsules

Shelf life 2 years

Veterinary identification number: **α PL0614003p**

Date of the leaflet - 21.11.2017.

Marketing authorisation holder
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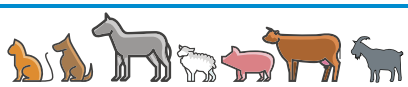
Injectio Glucosi 40%

PRODUCT AMELIORATING ENERGY DEFICITS

Solution for injections

Glucose monohydrate 400 mg/ml



Active substance and excipient content Glucosum monohydricum 400 mg/ml

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 – 312.5 ml
Sheep, goats, swine	12.50 – 25.00 g	31.0 – 62.5 ml
Dogs, cats	1.25 – 7.50 g	3.0 – 19.0 ml

Therapeutic indications

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

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.

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

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 life-threatening 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. To be administered under veterinary supervision.

Marketing authorisation 752/99

2015-05-07 SPC

Marketing authorisation holder

Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,

e-mail: sekretariat@biowet.pl, www.biowet.pl

BIOWET Biowet PUŁAWY

Injectio Pyralgini
Biowet Puławy

ANALGESIC, ANTISPASMODIC, ANTIINFLAMMATORY AND ANTIPYRETIC AGENT

Solution for injections for horses, cattle, swine 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.

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..
Swine	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.

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

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: 4 days
Swine: Edible tissues: 12 days after the intravenous administration
20 days after the intramuscular administration
Dogs: not applicable.

Marketing authorisation holder
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Biowet PUŁAWY

Injectio Pyralgini
Biowet Puławy

ANALGESIC, ANTISPASMODIC, ANTIINFLAMMATORY AND ANTIPYRETIC AGENT

Solution for injections for horses, cattle, swine and dogs
Metamizole sodium 500 mg/ml

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.
Interactions with other medicinal products or other forms of interaction:
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 no longer required. These measures should help to protect the environment.

Shelf life 2 years
Available containers: 50 ml, 100 ml.

For animal treatment only. Subject to medical prescription – prescription drug. To be administered only by a veterinary surgeon.
Marketing authorisation 201/95
2016-01-20 SPC

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Insectin

POWDER FOR CONTROLLING INFESTATION OF ECTOPARASITES (FLEAS, TICKS, BITING LICE, SOFT TICKS)

Skin and coat powder for dogs and cats

Permethrin 10 mg/g

Active substance content

Permethrin (as permethrin 25:75 cis:trans isomer ratio) 10 mg/g

Therapeutic indications

Insectin is designed to combat ectoparasites invasion: fleas and ticks in dogs, lice and pigeon ticks in pigeons.

Posology per each species, routes and methods of administration

Small dog: 5–10 g
Medium-sized dog: 10–15 g
Big dog: 15–20 g
Pigeon: 1–2 g

10 applications – drops from an inverted container mean application of 2.5-3.0 g of the product on skin.

Recommendations for proper administration

Apply the product externally to the skin.
Sprinkle the entire animal body with the powder, setting the hair or feathers apart to reach the skin. Avoid sprinkling eye, ear, nose and muzzle area with the powder. Leave the product for a few hours, next brush out the coat.
Exchange animal bedding after each treatment procedure. Repeat the procedure after 2-3 weeks.

Contraindications

Do not use in puppies aged less than 12 week. Do not use in lactating female dogs. Do not use in pigeons aged less than 1 month. Do not use in cats. The product may produce serious adverse reactions including death; therefore prevent cat's contact with the product. If dogs and cats are kept together, isolate cats for 72 hours since the end of treatment. Make sure that cats do not lick the coat of a dog undergoing treatment. Should that occur, immediately seek advice of a veterinary doctor. Do not use in case of hypersensitivity to the active substance or any excipient.

Adverse reactions

Dogs rarely experience undesirable side effects such as excessive drooling, vomiting, diarrhoea, moderate muscular tremor and hyperactivity transforming into depression. Birds are mildly susceptible to permethrin. Undesirable effects related to stimulation of the nervous system appear extremely rarely. 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 5

Withdrawal period

Dog – not applicable. Do not use in pigeons intended for human consumption.

Special precautions for storage

Keep out of the sight and reach of children. Store in a dry place, at a temperature below +25°C. Keep away from food for people and feed for animals. Do not use this veterinary medicinal product after the expiry date given on the label. The expiry date refers to the last day of that month.

Special warnings

Special warnings per each target species:
For external use only. Do not rub the product into animal skin.
For the most effective flea elimination, it is recommended to use a proper insecticide in dog's place of stay (bedding, kennel disinfection, etc.). In addition, combating fleas in all animals kept together at the same time is recommended.
Special precautions for use in animals:
Do not allow animals to lick the product off. During the procedure, protect eyes of the animals.
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The procedure should be performed outside the accommodation. Avoid excessive dusting and inhalation of the product. During procedures, use generally accepted precautions for handling insecticides; in particular, the use of protective gloves and masks is recommended. Avoid contact with eyes. After the procedure, wash hands thoroughly. In case of accidental contact with the skin or mucous membranes, immediately flush the affected site with pure water. Protect children from contact with the product and with animals undergoing treatment. Do not allow animals treated with the product to play with humans, especially children, until the product is removed from body surfaces.
Individuals with a diagnosed hypersensitivity to permethrin should avoid contact with the veterinary medicinal product.
Other precautions:
Do not allow dogs undergoing treatment to immerse in water bodies for at least 3 weeks of product administration.
Pregnancy and lactation: Do not use the product in pregnant and lactating animals.
Egg laying: Do not use the product during egg laying period.
Interactions with other medicinal products and other forms of interaction: Unknown.
Overdose (symptoms, procedures concerning immediate help and antidotes):
In case of overdose, intensive symptomatic treatment should be applied, as no specific antidote has been developed. Administration of tranquilizers, anticonvulsants (diazepam, pentobarbital, propofol) and muscle relaxants is recommended. Replenish the liquids by administration of crystalloids (sodium chloride physiological solution or multi-electrolyte solution). It is also recommended to bathe the poisoned animal in tepid water with addition of soft

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Insectin

POWDER FOR CONTROLLING INFESTATION OF ECTOPARASITES (FLEAS, TICKS, BITING LICE, SOFT TICKS)

Skin and coat powder for dogs and cats

Permethrin 10 mg/g

detergents, in order to wash any permethrin residues off the skin.

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

Veterinary medicinal product extremely toxic for bees, fish and crustaceans. 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 50 g.

Shelf life 2 years

Product available on non-prescription basis – OTC.

For use by the owner or the carer of the animal.

Only for animals

Marketing authorisation 742/99

2015-02-02 SPC

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Ketamina Biowet Puławy

PRODUCT FOR ANAESTHESIA DURING SURGICAL PROCEDURES

Solution for injections for cats and dogs
Ketamine 100 mg/ml

Active substance and excipient content 1 ml contains:
Active substance: ketamine 100 mg (in the form of ketamine hydrochloride 115.34 mg)
Excipient: Chlorobutanol hemihydrate 3 mg

Therapeutic indications
Short-lasting general anaesthesia for minor procedures 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. Full anaesthesia with premedication using anaesthetics to achieve general anaesthesia, for example in operations of fractures, reduction of dislocation, castration, amputation, caesarean section, laparotomy.

Posology for each species, routes and methods of administration
Ketamine is administered intravenously or intramuscularly. Before administration of ketamine, perform premedication using atropine in the dose of 0.05 mg/kg b.w. intramuscularly or subcutaneously.
Dosage for dogs:
2-5 mg of ketamine/kg b.w. intravenously
5-15 mg of ketamine/kg b.w. intramuscularly
Dosage for cats:
5-15 mg of ketamine/kg b.w. intramuscularly
Administration of ketamine in combination with other anaesthetics and premedication drugs before general anaesthesia:

Effective anaesthesia

Ketamina Biowet Puławy:

- short-lasting general anaesthesia to facilitate minor procedures requiring analgesia
- full anaesthesia combined with other anaesthetics

Cats: administer atropine intramuscularly in the dose of 0.05 mg/kg b.w., then xylazine or diazepam and after several minutes administer ketamine in the dose of 5-15 mg/kg b.w.
Dogs: administer atropine intramuscularly in the dose of 0.05 mg/kg b.w., then a neuroleptic agent (diazepam, medetomidine or xylazine) and after 5-10 minutes administer 3 mg of ketamine/kg b.w. intravenously or 10 mg of ketamine/kg b.w. intramuscularly.
After intramuscular administration, full anaesthesia is achieved within 3-5 minutes. Normally, the duration of ketamine effect is 20-45 minutes. The higher the dose, the longer the duration of anaesthesia. The dose size has no effect on the depth of anaesthesia.
After approx. two hours, most animals are able to stand up.

Recommendations for proper administration
In the case of intravenous administration, the preparation should be warmed to body temperature and injected slowly.

Contraindications
Do not use in animals with circulatory insufficiency, hypertension, hepatic or renal damage. Do not use in animals with epilepsy, ocular hypertension, open-globe injuries and head injuries. Do not use in the case of hypersensitivity to ketamine or chlorobutanol.

Adverse reactions
Ketamine causes hypertension, tachycardia, moderate respiratory depression, may cause a cardiac arrest. Ketamine administration might be followed by: increased salvation, increased muscle tone, possible vomiting, convulsions, spastic movements and tonic spasms, nystagmus and pupil dilation as well as pulmonary oedema. Disappearance of blink reflexes after ketamine administration may lead to corneal dryness. Vocalisation may occur during recovery. 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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Withdrawal period
Not applicable

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Biowet PUŁAWY

Ketamina
Biowet Puławy

PRODUCT FOR ANAESTHESIA DURING SURGICAL PROCEDURES

Solution for injections
Ketamine 100 mg/ml

Special precautions for storage
Keep out of the reach and sight of children. Store below 25°C. 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 warnings concerning each of the target animal species:
Animals should not be fed any food within 12 hours before application of the product. Abdominal surgeries require administration of the appropriate analgesic because ketamine does not eliminate enteroception. Because ketamine does not remove laryngeal reflex, increases salivation and production of tracheal and bronchial secretion in procedures on the rhinopharynx, larynx, trachea and bronchi as well as in endoscopy, the drug should be used in combination with agents removing the aforementioned effects of ketamine.
Special precautions for use in animals:
Ketamine may increase salivation and secretion in the respiratory tract, which may lead to choking and obstruction of the respiratory tract.
During anaesthesia, one must remember to secure the eye against corneal dryness. During the recovery of animals anaesthetised using ketamine, the following symptoms might occur: hallucinations, delirium, motor ataxia, hypersensitivity to touch, overreactivity, aggression. During recovery, animals should be provided with peace and quiet and protection against self-mutilation.
In the case of excessive blood loss, the ketamine dose should be reduced.
Since ketamine increases the heart rate and the heart's demand for oxygen, it must be used with caution in patients with myocardial disease.
Ketamine causes moderate respiratory depression, frequently reduces the respiratory rate and respiratory volume. After ketamine administration, a characteristic type of respiration occurs, that is long periods of apnoea after inspiration. Therefore, during anaesthesia, the cardiac and pulmonary functions should be monitored.
Special precautions for persons administering the veterinary medicinal product to animals:
Ketamina Biowet Puławy is a product with a very potent effect. Particular caution should be taken to avoid self-injection. In the case of accidental self-injection by a person administering the product, anaesthesia might occur and after approx. 10 minutes loss of consciousness for 10 to 15 minutes. Amnesia and hallucination might occur on recovery. In the case of accidental self-injection, immediately seek medical advice and show the package leaflet or the label to the physician. Do not drive any vehicles. After an accidental contact with skin or mucosa, immediately wash the site with water.
Pregnancy: Do not use in pregnant animals, excluding a caesarean section.
Lactation: Do not use in lactation.

Interaction with other medicinal products and other forms of interaction
Xylazine, detomidine, medetomidine, acepromazine prevent the occurrence of convulsions which may accompany ketamine anaesthesia.
Ketamine effect is intensified by other agents that weaken the function of the central nervous system.
Narcotic agents, barbiturates, diazepam may prolong recovery.
Chloramphenicol may prolong the anaesthetic effect of ketamine.
Neuromuscular blockers, e.g. succinylcholine and tubocurarine, may intensify or prolong respiratory depression.
Thiopental prevents ketamine-induced stimulation of cerebral metabolism and dilation of cerebral vessels. Atropine prevents excessive salivation occurring after administration of ketamine.
Overdose (symptoms, procedures concerning immediate help and antidotes):
Exceeding the recommended doses leads to respiratory depression. A dose that is eight times higher than the recommended one causes paralysis of the respiratory system whereas a dose that is twelve times higher leads to circulatory arrest.
Administration of too high doses of the drug might induce vomiting and muscle tremor.
In the case of an overdose, mechanical resuscitation methods should be considered – respiration must be maintained and cardiac massage must be applied.
Pharmaceutical incompatibilities:
Ketamine should not be used with barbiturates due to their chemical incompatibility.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with applicable regulations.

Shelf life 2 years
For animal treatment only. Subject to medical prescription – prescription drug.
To be administered under veterinary supervision.
Possession and sales of the product are regulated by regulations concerning products containing narcotic drugs or psychotropic substances.
Available containers 50 ml and 10 ml
Marketing authorisation 319/97
2016-05-16 SPC

Marketing authorisation holder
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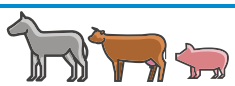
e-mail: sekretariat@biowet.pl, www.biowet.pl

Lydium-KLP

Solution for injection for horses, cattle, pigs
Lysozyme dimer 5 mg/10 ml



Statement of active and other substances 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.
Cattle: To support treatment of bacterial and viral infections, in particular gastrointestinal and respiratory inflammations, as well as mammary gland, skin and outer ear inflammations.
Pigs: 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).

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.
Cattle: 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.
Pigs: 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.

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

Advice on correct administration None.

Withdrawal period Zero days.

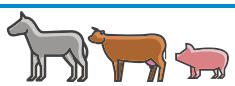
Special precautions for storage Keep out of the reach and sight of children. Store below 20°C. Do not freeze. Shelf life after first opening the immediate packaging – once opened, use immediately. Do not use after the expiry date stated on the label and outer package.

Special warnings Special precautions to be taken by the person administering 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.

Distributor
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Lydium-KLP

Solution for injection for horses, cattle, pigs
Lysozyme dimer 5 mg/10 ml



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 any information on this veterinary medicinal product, please contact the marketing authorisation holder.
Nika Health Products Sp. z o.o., Parsko 12, 64-030 Śmigiel, Tel.: +48 65 518 56 08, Mobile: +48 505 15 11 13, e-mail: biuro@nikahp.pl
Pack sizes 5 glass bottles in a cardboard box.
Shelf life 4 years
SPC 2016-11-22

Distributor
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

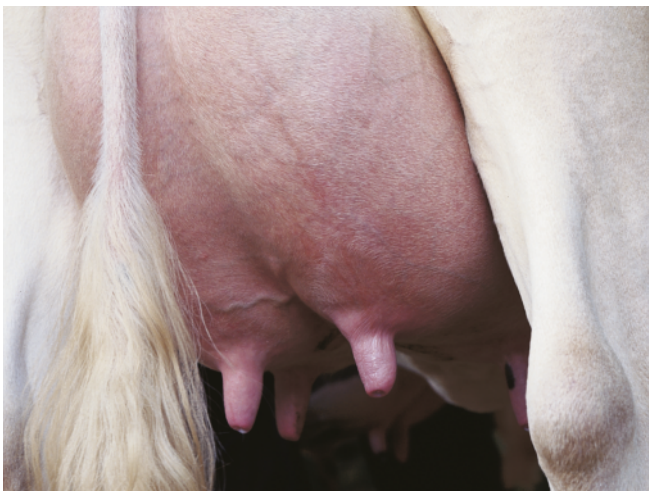
Mastiprewent®

OINTMENT FOR UDDER CARE

Udder care preparation for use in cows and goats.

Ingredients
Eucalyptus oil, camphor, menthol, eucerinum, yellow petroleum jelly.
Indications and use
The product is recommended for udder care in cows and goats.
It should be used externally – after every milking, by applying and massaging the formula into the skin of udder and teats. Regular product use ensures proper flexibility and prevents drying and cracking of the skin of udders and teats. Due to specific properties, the product may also be used in inflammations caused by, e.g. stinging by insects, eczema, abrasion, etc.
Contraindications
Prevent direct exposure of mucous membranes to the product.

Prevention, protection, care



Mastiprewent

- Reduces irritation caused by insect bites and prevents cracking of udder and teat skin
- Eucalyptus oil ensures strong antiseptic effect and elasticity of udder and teat skin
- Camphor has a warming effect, and causes hyperaemia of subcutaneous tissues with stimulation of granulation
- Menthol causes a cooling sensation and reduces sensitivity of nociceptors

Storage
Store at a temperature below +25°C. Protect from light. *Keep out of the reach and sight* of children.
Shelf life 24 months
Available containers 250 g and 500 g
Date of development of the leaflet - 09.11.2015 r.

Marketing authorisation holder
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e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Mlek-test®

DIAGNOSTIC TEST FOR DETECTION
OF INCREASED NUMBER OF SOMATIC CELLS
AND PH ASSESSMENT IN RAW MILK

Formula for detecting high somatic cell count and determining raw milk acidity (pH)

Ingredients
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 degrees. 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)

RESULT	APPEARANCE OF MIXTURE	CELL COUNT in 1 ml
Negative*	Liquid or tufts and trails vanishing during mixing. Greyish-violet.	Up to 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.

Quick way to test milk

Mlek-test

- allows approximate assessment of the level of milk acidification - pH of milk stored in a cistern
- facilitates detection of subclinical inflammatory states of the udder
- allows determination of the level of somatic cells from 400 thousand in 1 mL of milk

Shelf life: 2 years.
Storage Store at below 25°C. 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
Date of development of the leaflet - 09.11.2015 r.

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Morbital

PRODUCT FOR EUTHANASIA

Solution for injection for dogs and cats

Active substance and excipient content **1 ml of the product contains:**

Active substances:

Sodium pentobarbital – 133.3 mg/ml

Pentobarbital – 26.7 mg/ml

Therapeutic indications

Euthanasia of dogs and cats.

Posology per each species, routes and methods of administration

The recommended route of administration is the intravenous administration. Intraperitoneal administration is acceptable if intravenous administration is impossible or dangerous. Intracardial administration is permissible only in animals in full sedation which are unconscious or anaesthetised. In rapid administration of Morbital (preferably intravenously), the animal falls asleep with no adverse effects. Within slightly over ten seconds, respiration ceases and cardiac arrest occurs. Corneal reaction may remain up to 1.5 minutes.

Morbital administration:

	Morbital	Sodium pentobarbitone	Pentobarbitone
Intravenous	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	1.0-2.0 ml/kg b.w.	133.3-266.6 mg/kg b.w.	26.7-53.4 mg/kg b.w.
Intracardial	0.3-0.6 ml/kg b.w.	39.99–79.98 mg/kg b.w.	8.01-16.02 mg/kg b.w.

Recommendations for proper administration

The recommended route of administration with the smallest and shortest pain is the intravenous administration.

Intraperitoneal administration is acceptable if intravenous administration is impossible or dangerous. Using this route, animals may slowly become sedated and anaesthetised. Therefore, peace and quiet should be provided for them.

In timid, aggressive or wild animals, premedication is recommended. Intracardial administration may only be used in exceptional cases in animals in full sedation which are unconscious or anaesthetised.

The preparation should be injected evenly, quickly administering optimal doses. Administration of an incomplete dose may induce symptoms of prolonged sleep with possible awakening.

The bodyweight of an animal has to be determined as accurately as possible before the procedure. Lower doses per 1 kg are effective in adult dogs as well as sick and starving dogs.

In each case, make sure whether the death of the animal has taken place since deep anaesthesia may simulate symptoms of death.

Contraindications

Do not administer intrapulmonarily, intrapleurally and intramuscularly. Do not use for anaesthesiology. Do not use in animals whose tissues are intended for human consumption.

Adverse reactions

During the use of the preparation, temporary excitement and breathlessness symptoms 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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Withdrawal period

Not applicable.

Special precautions for storage

Keep out of the sight and reach of children. Store at a temperature below 25°C. Do not use this veterinary medical product after the expiry date given on the label. The durability period after the first opening of the immediate container: 28 days.

Special warnings

Special precautions for use in animals:

After accidental administration of the product to animals not intended for euthanasia, immediately begin actions supporting respiration, administer oxygen and analeptics.

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

People with diagnosed hypersensitivity to barbiturates should avoid contact with the product.

Particular caution should be taken to avoid direct contact during administration. If the product gets into the airways, immediately go into fresh air. In the case of the contact of the product with the skin, wash the site with water and soap and change clothes if they have been stained with the product. In the case of the contact of the product with eyes, immediately wash eyes with plenty of water. On swallowing of the product, subcutaneous or intramuscular administration, its rapid absorption occurs. After swallowing of the product or parenteral administration, you should always immediately seek medical help and show the leaflet or the package to a physician. A person exposed to the effect of the product should not drive due to the possibility of sedation, breathlessness and changes in arterial blood pressure and should remain under the supervision of another person.

Information for physicians

The product contains pentobarbital in such an amount that injection or consumption of 2.5 ml may cause serious symptoms from the central nervous system in an adult person. One gram of pentobarbital (which nearly corresponds to 7 ml of the product) may cause a person's death. Symptomatic treatment and treatment consisting in maintaining primary life functions should be applied in a person who has been exposed to the effect of the product.

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Morbital

Solution for injection for dogs and cats

Other precautions
Consumption of meat of animals subjected to euthanasia using Morbital is dangerous. This might cause deep narcosis or death. This also applies to meat subjected to heat processing as barbiturates are resistant to high temperatures. Therefore, corpses of euthanized animals must not be intended for consumption by other animals, but should be disposed of in accordance with valid regulations.
Pregnancy
If the product is used in pregnant females, the death of the mother causes the death of the foetus.
Interactions with other medicinal products and other forms of interaction:
Barbiturates intensify the inhibitory effect on neurotransmission in the neuromuscular junction induced by d-tubocurarines and hexamethonium. Moreover, pentobarbitone and streptomycin induce additive reactions causing dilatation of vessels, mainly renal vessels. Intravenous administration of a calcium solution removes the vasodilating effect allowing the use of sodium pentobarbitone in animals treated with streptomycin. Interactions with some amino glycosides were also demonstrated.
Overdose (symptoms, procedures concerning immediate help and antidotes):
Not applicable.
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.
Available containers 100 ml.
Shelf life 2 years
Subject to medical prescription – prescription drug. Only for animals.
To be administered under veterinary supervision.
Other information
To be administered under veterinary supervision.
Possession and sales of the product are set out in regulations concerning preparation containing intoxicants or psychotropic substances.
For more information about this veterinary medicinal product, contact the Marketing Authorization Holder.
Marketing authorization 651/99
2016-09-14 SPC

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Biowet PUŁAWY

Mycosalmovir

VACCINE AGAINST SALMONELLOSIS, PARAMYXOVIROSIS AND MYCOPLASMOSIS OF PIGEONS

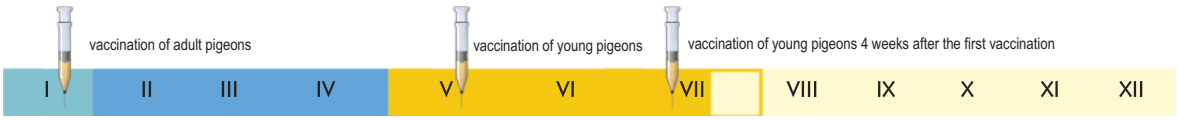
Inactivated vaccine against salmonellosis, paramyxovirosis and mycoplasmosis of pigeons

Emulsion for injection for pigeons

Active substances and excipients 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. typhimurium var. 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.

Healthy flight for victory



Before vaccination
A few days before vaccination, use Immunex complex - preparation improving performance of the immune system. Before vaccination of adult pigeons, do not feed them about 3 hours and do not give them water about 60 minutes prior to vaccination.

Vaccination
Prophylactic vaccination should be performed only in healthy flocks of pigeons. Do not vaccinate birds which are sick, in poor condition, infested, or attacked by Trichomonas (yellow mass). Do not vaccinate pigeons in the period of laying and moulting

Adult pigeons
Vaccination of adult pigeons, which were repeatedly immunised, should be performed about 2-3 weeks before pairing or exhibitions.
Full resistance is developed about 21 days after vaccination.

Young pigeons
Young pigeons should be vaccinated twice, with a 4-week interval, when they reach 3-4 weeks of life. Second vaccination - injection not later than 3 weeks before flights.

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.

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

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BIOWET Biowet PUŁAWY

Inactivated vaccine against salmonellosis, paramyxovirosis and mycoplasmosis of pigeons

Emulsion for injection for pigeons

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

Withdrawal period Zero days.

Special precautions for storage Keep out of the reach and sight of children.Store in a refrigerator (2-8°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.

Interactions with other medicinal products or other forms of interactions: 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.

Size of the container 50 doses, 100 doses

Shelf life 18 months

Only for animals. Prescription-only-medicine. For administration only under the supervision of a veterinary surgeon.

Marketing authorisation number 986/00

SPC 2015.08.20

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
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Oticlar®

Ear cleaning lotion for dogs and cats

Ingredients
Xylene, glycerol, menthol, thymol and propylene glycol.
Characteristics and effect
As a ceruminolytic, xylene ensures excellent breaking-up of earwax. Softening and soothing effect brought by glycerol and propylene glycol help active substances penetrate the ear canal, and ensure excellent tolerance of the solution. Glycerol has strong dissolving properties.
Menthol and thymol produce antiseptic and dehydrating effect (they produce scent). This makes OTCLAR an excellent ear care solution for cats and dogs.
Indications
OTICLAR may be used in regular ear cleaning in cats and dogs, once to twice a week. In ear diseases, the product is usually applied as a pre-cleansing agent to the ear canal, before applying the proper drug, as excessive earwax may weaken the effect of the key medicinal product.

Ear hygiene in dogs and cats

Oticlar

- softens and dissolves earwax
- facilitates penetration of the drug active substances
- ameliorates and reduces itching
- cleans and cares

Directions for use Apply externally. Introduce a few ml portions into ear canal and cleanse, repeating the procedure until the ear is completely cleaned. If earwax is produced excessively, re-apply the product once or twice a day for three consecutive days without any risk of complications. In dogs (especially droopy-eared) suffering from chronic outer ear inflammation, daily use ensures faster recovery.
Contraindications
Do not use in labyrinthitis. In case of outer ear inflammation, use the product for pre-cleaning purposes before application of appropriate medicinal product. Do not use in animals with skin hypersensitive to product ingredients (allergic).
Storage Store at a temperature not exceeding 25°C. Keep out of the reach and sight of children.
Shelf life 2 years.
Available containers 50 ml bottles.
For animal treatment only
Date of development of the leaflet-25.10.2013 r.

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Oxytan 200

Solution for injection for cattle, sheep and swine
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.

Focused on effect

Oxytan 200

- broad-spectrum activity
- good penetration of tissues with difficult access
- **single injection**
- long-term effect
- used during lactation

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. Swine: 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.

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

Withdrawal period
Cattle: Meat and offal – 31 days. Milk – 10 days.
Sheep: Meat and offal – 9 days. Milk – 7 days.
Swine: Meat and offal – 18 days

Special precautions for storage
Keep out of the reach and sight of children. Store at a temperature below 25°C. 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.

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Biowet PUŁAWY

Oxytan 200

Solution for injection for cattle, sheep and swine

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. 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.

Interactions with other medicinal products or other forms of interactions: 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): Exceeding the recommended dose might induce hepatotoxic and nephrotoxic effect of the drug. 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 dose of medicines no longer required. These measures should help to protect the environment.

Shelf life 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.

2015-12-01 SPC

Marketing authorisation holder
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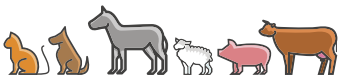
Oxytocinum
Biowet Puławy

HORMONAL PRODUCT

Solution for injection for cattle, horses, swine, sheep, dogs and cats

Oxitocin 10 IU/ml



Active substance and excipient content 1 ml contains:
Active substance: oxytocin 10 IU
Excipient: chlorobutanol hemihydrate 5 mg

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.

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 http://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 and horses: 3-5 ml (which corresponds to 30 – 50 IU),
swine, sheep: 2-3 ml (which corresponds to 20 – 30 IU),
dogs: 0.5-1.5 ml (which corresponds to 5 – 15 IU),
cats: 0.3-0.5 ml (which corresponds to 3 – 5 IU).
In justified cases, the product can also be administered intravenously. However, reduction of the dose to approx. ¼ 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

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

Withdrawal period
Meat and offal: 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 2ºC – 8ºC. 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. Oxytocin is contraindicated in the last stage of pregnancy due to the risk of miscarriage.
Interactions with other medicinal products and other forms of interaction:
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.

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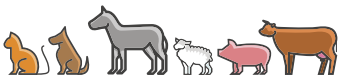
BIOWET Biowet PUŁAWY

Oxytocinum
Biowet Puławy

HORMONAL PRODUCT

Solution for injection for cattle, horses, swine, sheep, dogs and cats

Oxitocin 10 IU/ml



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.

Size of the container Containers: 50 ml, 100 ml

Shelf life 2 years

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

Other information

Marketing authorisation 45/94

2015-01-21 SPC

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PM-VAC

INACTIVATED VACCINE AGAINST PIGEON PARAMYXOVIROSIS

Emulsion for injection for pigeons

Active substance and excipient content One dose (0.2 ml) of the vaccine contains: Inactivated PMV-1 (LaSota strain) – no less than 1 ELISA unit
1 ELISA unit – the quantity of antigen sufficient to obtain seroconversion equal to or higher than 1.8 in a vaccinated pigeon
Adjuvant: Liquid paraffin – 109 mg

Therapeutic indications
The vaccine is intended for active immunisation of pigeons in order to reduce mortality, clinical symptoms and pathological lesions induced by paramyxovirus. Postvaccinal immunity occurs 21 days after immunisation and remains for approximately 12 months.

Posology for each species, route and method of administration
The vaccine should be administered in a single subcutaneous injection. 1 dose equals to 0.2 ml of oil emulsion. The vaccine is used in young pigeons aged over three weeks, but not later than two weeks before flights of the young or exhibitions. Adult pigeons should be immunised every 12 months. The preferable time for vaccinations is the period of two-three weeks before mating. The dose for one pigeon, regardless of the age, is 0.2 ml of the oil emulsion which should be injected subcutaneously in the middle of the dorsal part of the neck.

Recommendations for proper administration
Before administration, the phial with the vaccine should be warmed to room temperature and mixed thoroughly. Administration procedures should be performed at an ambient temperature not lower than 0°C. Annual re-vaccination of the birds is recommended.

Contraindications
Verminous pigeons should not be vaccinated as well as pigeons in the moulting period. Do not use in pigeons treated with immunosuppressive agents.

Adverse reactions
Rarely reported adverse effects are temporary lack of appetite and apathy occurring within several hours after administration of the product and a temporary local reaction in the form of a small tuber that spontaneously disappears within several days. Hypersensitivity reactions might occasionally occur. Proper treatment consisting in immediate administration of adrenaline and antihistamine drug should be applied in this case. 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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Withdrawal period Zero days.

Special precautions for storage Keep out of the reach and sight of children. Store in a refrigerator (2-8°C). Do not freeze. Protect from light. The content of the immediate container should be used within 10 hours after opening. 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 for persons administering the medicinal veterinary product to animals:
For the user:
This medicinal veterinary product contains mineral oil. Accidental self-injection may cause excessive pain and swelling, especially when injected into a joint or a finger, and in rare cases may lead to the loss of the finger if immediate medical aid is not provided. In the case of accidental self-injection of the medicinal veterinary product, 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.
For the physician:
This medicinal veterinary product contains mineral oil. Even if only a very small dose of the product has been injected, it may cause excessive pain and swelling and, in consequence, digital infarct or even a loss of the finger. Professional and IMMEDIATE surgical aid involving early incision and irrigation of the injection site, especially if it concerns the digital pulp or the tendon, is indispensible.
Laying period: The vaccine should not be used during the laying period.

Interaction with other medicinal products and other forms of interaction:
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, procedures concerning immediate help and antidotes): After administration of a double dose, no other adverse effects occurred than those specified in the section concerning adverse reactions.
Pharmaceutical incompatibilities: 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.

Available containers 20 ml glass bottle containing 100 vaccine doses, packaged single in a cardboard box.

Shelf life 18 months

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

Marketing authorization 743/99
SPC 2015-05-07

Marketing authorisation holder
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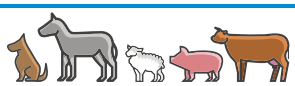
BIOWET Biowet PUŁAWY

Polisulfalent®

PRODUCT FOR USE IN BACTERIAL INFECTIONS

Solution for injection for horses, cattle, swine, sheep and dogs



Active substances and excipients content 1 ml contains:

Active substance:

Sulphamethoxine sodium – 77 mg/ml
Sulphadimidine sodium – 30 mg/ml
Sulfatiazole sodium pentahydrate -18 mg/ml

Excipient: chlorocresol – 2 mg

Therapeutic indications

Horses:

– primary and secondary bacterial infections of the respiratory tract caused by *Staphylococcus*, *Streptococcus* spp., *Rhodococcus equi, Actinobacillus equi, Pasteurella* spp.,
– infections of the gastrointestinal tract caused by *Rhodococcus equi, Actinobacillus* spp., *Salmonella* spp. excluding cases with symptoms of dehydration
– infections of the urinary tract caused by *Streptococcus* spp., *Actinobacillus* spp., *Salmonella* spp.,
– infections of the reproductive tract caused by *Streptococcus* , *Escherichia coli, Klebsiella pneumoniae, Salmonella abortus equi, Taylorella equigenitalis,*
– infections of soft tissues caused by *Staphylococcus* spp., *Streptococcus*,

Cattle, sheep:

– primary and secondary bacterial infections of the respiratory tract caused by *Haemophilus somnus, Mannheimia haemolitica*, *Pasteurella multocida,*
– enzootic bronchopneumonia of calves caused by *Mannheimia haemolitica*,*Pasteurella multocida,*
– colibacteriosis in calves caused by *Escherichia coli,*
– diphtheroid inflammations caused by sensitive strains *Fusobacterium necrophorum,*
– mastitis caused by *Staphylococcus* spp., *Streptococcus* spp., *Escherichia coli,*
– infections of the reproductive tract caused by *Staphylococcus* spp., *Streptococcus* spp., *Escherichia coli, Haemophilus somnus,*

Swine:

– primary and secondary bacterial infections of the respiratory tract caused by *Streptococcus suis,Actinobacillus pleuropneumoniae, Actinobacillus suis, Bordetella bronchiseptica, Haemophilus parasuis, Pasteurella multocida,*
– infections of the gastrointestinal tract caused by *Escherichia coli*, *Salmonella choleraesuis,*
– infections of the reproductive tract (incl. MMA syndrom) caused by *Staphylococcus*, *Streptococcus* spp., *Escherichia coli, Klebsiella* spp.,

Dogs:

– primary and secondary bacterial infections of the respiratory tract caused by *Staphylococcus*spp., *Bordetella bronchiseptica, Klebsiella* ,
– intestinal infections caused by *Escherichia coli, Salmonella* spp,
– urogenital infections caused by *Staphylococcus* spp, *Klebsiella*spp, *Proteus* spp,
– infections of the reproductive tract caused by*Staphylococcus* spp, *Klebsiella* spp., *Proteus*spp.,
– infections soft tissues caused by *Staphylococcus* , *Streptococcus* spp., *Proteus* spp.

Posology and routes of administration

Polisulfalent may be administered intravenously, intramuscularly, intraperitoneally and subcutaneously.

Posology: horses, cattle, swine, sheep, dogs:

Initial dose (first day of treatment): 45-112 mg of sulphonamides/kg b.w., i.e. 0.4-1.0 ml of Polisulfalent/kg b.w.,
It is best to administer the first dose intravenously in order to obtain a high blood concentration of the drug.
In the successive days of treatment, 2/3 – 1/2 of the initial dose is administered. The duration of treatment with Polisulfamid, whose efficacy has been confirmed with an antibiogram, is 5-7 days.

Recommendations for proper administration

Administration of an insufficient dose or too short therapy leads to development of microbial resistance to sulphonamides. For that reason, purposefulness of sulphonamide use must be confirmed by antibiogram results. During treatment, animals should be given profuse amounts of water or provided with unlimited access to water, in order to prevent crystalluria development. Polisulfalent administered intramuscularly or subcutaneously should be injected in a number of different sites, and in case of intravenous administration, the product should be warmed up to body temperature. Intravenous injection should be made slowly.

Contraindications

Do not use in the case of sensitivity to the active substances or to any excipient. Do not use in animals with renal and hepatic insufficiency, diseases of the haematopoietic system, in dehydrated animals or in the case of limited water intake by the animal. Do not use in pregnant females and very young animals.

Adverse reactions

The product may cause impaired urination, opaque urine, haematuria and in animals hypersensitive to sulphonamides – haematuria and apathy. When administered intramuscularly or subcutaneously, the product may cause local reactions in the form of swelling. Side effects of sulphonamides may be expressed by hypersensitivity reactions or a direct toxic effect. Hypersensitivity reactions may be manifested by the occurrence of urticaria, anaphylaxis, fever, arthritis, haemolytic anaemia, agranulocytosis and cutaneous lesions. Sometimes haematuria and obstruction of renal tubules may occur. In general, highly soluble long-acting sulphonamides do not cause crystalluria. Rapid intravenous infusion exerts a toxic effect, manifested by such clinical symptoms as muscle weakness, ataxia, blindness and collapse. Sometimes gastrointestinal disorders may occur as a consequence of the bacteriostatic impact of

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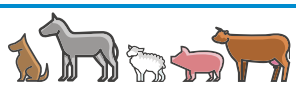
BIOWET Biowet PUŁAWY

Solution for injection for horses, cattle, swine, sheep and dogs



sulphonamides on the microflora of the gastrointestinal tract. This situation particularly refers to ruminants, in which, as a result of bacteriostasis of the microflora of forestomachs, vitamin B synthesis may also be disrupted. Long-term administration of sulphonamides may also lead to bone marrow damage, and consequently, to aplastic anemia, granulocytopenia and thrombocytopenia. Long-term therapy with large drug doses may lead to the development of hepatitis, icterus, nerve inflammation, spinal cord and peripheral nerve degeneration, stomatitis and keratitis. In dogs, thymus hyperplasia or hypothyrodoism may occur as a result of drug administration. At times, sulphonamides may have a photosensibilizing effect. 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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Withdrawal period

Cattle: Meat and offal – 10 days. Milk – 5 days.
Sheep: Meat and offal – 10 days. Milk – 5 days.
Swine: Meat and offal – 10 days.
Dogs: not applicable.

Do not use in horses whose tissues are intended for human consumption. Horses treated with Polisulfalent can never be intended for human consumption. Only use in horses whose passport contains a declaration "not intended for slaughter for food preparation (human consumption) in accordance with the law"

Special precautions for storage

Keep out of the sight and reach of children. Store in a refrigerator (2°C – 8°C). Protects from light. Do not freeze. Do not use this veterinary medical product after the expiry date given on the label. The durability period after the first opening of the immediate container: 28 days.

Special warnings

Special warnings per each target species:

Provide unlimited access to drinking water in order to prevent crystallisation of sulfonamides in urine. Administration of an insufficient dose or too short therapy leads to development of microbial resistance to sulphonamides. For that reason, purposefulness of sulphonamide use must be confirmed by antibiogram results. Sulphonamides are less effective in purulent secretion and necrotic tissues.

Special precautions for use in animals:

The product should be used on the basis of results of the resistance tests for bacteria isolated from sick animals. If this is impossible, treatment should be performed on the basis of local epidemiological information concerning sensitivity of isolated bacteria. During treatment, animals should be carefully observed for symptoms related to problems with urination, opaque urine or haematuria. In animals hypersensitive to sulphonamides, haematuria or apathy may occur. In such cases, administration of the drug should be discontinued. Especially sensitive to the activity of sulphonamides are dogs, particularly of large breeds, which can experience hypersensitivity reactions. Polisulfalent administered intramuscularly or subcutaneously should be administered into various sites. In the case of intravenous administration, the preparation 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 the case of accidental self-injection, immediately seek medical advice and show the package leaflet or the label to the physician.

Pregnancy: Do not use during pregnancy.

Lactation: The product may be used during lactation.

Interactions with other medicinal products and other forms of interaction:

Do not use with urotropine and local anaesthetics from the group of 4-aminobenzoic acid esters. Do not combine with acetylsalicylic acid. Sulphonamides may transport drugs strongly binding with proteins, such as methotrexate, warfarin, phenylbutazone, thiazide diuretics, salicylates or probenecid. Therefore, concentrations of the listed drugs should be monitored. Simultaneous use of myelosuppressive drugs intensifies leucopoenia and thrombocytopenia. Combining them with hepatotoxic drugs enhances their negative effect on the liver. Since the bacteriostatic effect of sulphonamides may interfere with the bactericidal effect of penicillins, their simultaneous application is not recommended.

Overdose (symptoms, procedures concerning immediate help and antidotes):

Overdose leads to emergence of symptoms related to the nervous system, e.g. motor ataxia, considerable dejection and in case of acute poisoning – coma. Overdose may lead to circulatory failure. In cattle, acute poisoning may evoke shock symptoms, characterized by tremor, myatonia and vision disorders. Long-term administration of sulphonamides may also lead to bone marrow damage, and consequently, to aplastic anemia, granulocytopenia and thrombocytopenia. Long-term therapy with large drug doses may lead to development of hepatitis, icterus, nerve inflammation, spinal cord and peripheral nerve degeneration, stomatitis and keratitis. In dogs, thymus hyperplasia or hypothyrodoism may occur as a result of long-term drug administration. In case of overdose, symptomatic treatment should be applied.

Pharmaceutical incompatibilities: Since no conformity tests of this veterinary medicinal product have been conducted, this product must not be combined with other 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.

Available containers Glass bottle containing 250 ml of the product

Shelf life 3 years

For animals treatment only. Subject to medical prescription – prescription drug. To be administered under veterinary supervision.

Marketing authorization 744/99
2015-10-28 SPC

Marketing authorisation holder
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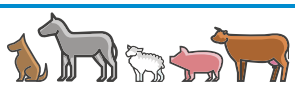
Polisulfamid®

PRODUCT FOR USE IN BACTERIAL INFECTIONS

Solution for injection for horses, cattle, swine, sheep and dogs



Active substances and excipients content 1 ml contains:
Active substance:
sodium sulfadimidine – 50 mg
sodium sulfacetamide – 40 mg
sodium sulfathiazole – 30 mg
Excipient: chlorocresol – 2 mg

Therapeutic indications

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.,*
– infections of the reproductive tract caused by *Streptococcus spp., Escherichia coli, Klebsiella pneumoniae, Salmonella equi,*
– soft tissue infections caused by *Staphylococcus spp., Streptococcus spp.*

Cattle:
– primary and secondary respiratory infections caused by *Haemophilus somnus, Mannheimia haemolytica* and *Pasteurella multocida,*
– enzootic bronchopneumonia in calves caused by *Mannheimia haemolitica, Pasteurella multocida,*
– colibacillosis in calves caused by *Escherichia coli,*
– diphtheroid inflammations in calves caused by sensitive strains of *Fusobacterium necrophorum,*
– mastitis caused by *Staphylococcus spp., Streptococcus spp., Escherichia coli,*

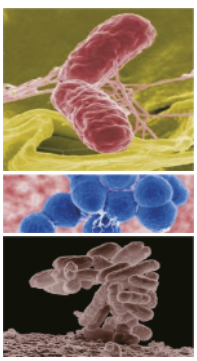
Sheep:
– respiratory infections caused by *Haemophilus somnus, Mannheimia haemolytica* and *Pasteurella multocida,*
– intestinal infections caused by *Escherichia coli,*

Swine:
– respiratory infections, including atrophic rhinitis caused by *Streptococcus suis, Actinobacillus pleuropneumoniae, Actinobacillus suis, Bordatella bronchiseptica, Haemophilus parasuis, Pasteurella multocida,*
– gastrointestinal infections caused by *Escherichia coli, Salmonella choleraesuis,*
– urogenital 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.,*
– intestinal infections caused by *Escherichia coli, Salmonella spp.,*
– soft tissue infections caused by *Staphylococcus spp., Streptococcus spp., Proteus spp., Nocardia spp.*

To kill the microbe

Actinobacillus pleuropneumoniae
Actinobacillus suis
Bordatella bronchiseptica
Escherichia coli
Fusobacterium necrophorum
Haemophilus somnus
Haemophilus parasuis
Klebsiella pneumoniae
Mannheimia haemolitica



Polisulfamid is a combination of three sulfonamides with different pharmacokinetic properties:

- Sodium sulfadimidine 50 mg **mid-long effect**
- Sodium sulfacetamide 40 mg **long half-life** (9-10 h)
- Sodium sulfathiazole 30 mg **short half-life** (3-4 h)

Posology for each species, routes and methods of administration
Polisulfamid is administered intravenously, intramuscularly, intraperitoneally and subcutaneously.
Posology: horses, cattle, swine, sheep, dogs:
The therapeutic dose of each substance:
sodium sulfadimidine 20 – 50 mg/kg b.w.
sodium sulfacetamide 16 – 40 mg/kg b.w.
sodium sulfathiazole 12 – 30 mg/kg b.w.
i.e. 48 – 120 mg of the combination of sulfonamides/kg b.w.
Doses in ml/kg b.w.:
horses, cattle, swine, sheep, dogs: 0.4-1.0 ml of Polisulfamid/kg b.w.
It is best to administer the first dose intravenously in order to obtain a high blood concentration of the drug.

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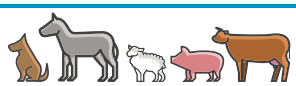
Polisulfamid®

PRODUCT FOR USE IN BACTERIAL INFECTIONS

Solution for injection for horses, cattle, swine, sheep and dogs



In the successive days of treatment, 2/3 – 1/2 of the initial dose is administered. The duration of treatment with Polisulfamid, whose efficacy has been confirmed with an antibiogram, is 5-7 days. Rapid intravenous infusion exerts a toxic effect, manifested by such clinical symptoms as muscle weakness, ataxia, blindness and collapse.

Recommendations for proper administration

During the treatment, animals ought to receive a lot of water and have easy access to water in order to prevent crystalluria. Polisulfamid administered intramuscularly or subcutaneously should be injected at various sites, and when administered intravenously, it should be warmed up to the body temperature. Intravenous injection should be made slowly.

Contraindications

Do not use in the case of sensitivity to the active substances or to any excipient. Do not use in animals with renal and hepatic insufficiency, diseases of the haematopoietic system, in dehydrated animals or in the case of limited water intake by the animal. Do not use in pregnant females or very young animals.

Adverse reactions

The product may cause impaired urination, opaque urine, haematuria and in animals hypersensitive to sulphonamides – haematuria and apathy. When administered intramuscularly or subcutaneously, the product may cause local reactions in the form of swelling. Side effects of sulphonamides may be manifested by hypersensitivity reactions or a direct toxic effect. Hypersensitivity reactions may be manifested by the occurrence of urticaria, anaphylaxis, fever, arthritis, haemolytic anaemia, agranulocytosis and cutaneous lesions. Sometimes haematuria and obstruction of renal tubules or crystalluria may occur. Rapid intravenous infusion exerts a toxic effect, manifested by such clinical symptoms as muscle weakness, ataxia, blindness and collapse. Sometimes gastrointestinal disorders may occur as a consequence of the bacteriostatic impact of sulphonamides on the microflora of the gastrointestinal tract. This situation particularly refers to ruminants, in which, as a result of bacteriostasis of the microflora of forestomachs, vitamin B synthesis may also be disrupted. At times, sulphonamides may have a photosensibilizing effect. 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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Withdrawal period

Cattle: Meat and offal – 10 days. Milk – 5 days. Sheep: Meat and offal – 10 days. Do not use in sheep whose milk is intended for human consumption.
Swine: Meat and offal – 10 days. Dogs: Not applicable. Do not use in horses whose tissues are intended for human consumption.
Horses treated with Polisulfamid can never be intended for human consumption. Only use in horses whose passports contain a declaration “not intended for slaughter for food preparation (human consumption) in accordance with the law”

Special precautions for storage

Keep out of the reach and sight of children. Store at a temp. of 2°C – 8°C. Protect from light. Do not freeze. 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 concerning each of the target animal species:
Administration of too low doses or too short therapy cause occurrence of bacterial resistance to sulphonamides. Therefore, use of sulphonamides must be justified by antibiogram results. Sulphonamides are less effective in purulent secretion and necrotic tissues. Special precautions for use in animals:
The product should be used on the basis of results of the resistance tests for bacteria isolated from sick animals. If this is impossible, treatment should be performed on the basis of local epidemiological information concerning sensitivity of isolated bacteria. Administration of sulphonamides may be followed by impaired urination, opaque urine or haematuria. Therefore, animals should be monitored attentively during the treatment. In animals hypersensitive to sulphonamides, haematuria or apathy may occur. In such cases, administration of the drug should be discontinued. Especially sensitive to the activity of sulphonamides are dogs, particularly of large breeds, which can experience hypersensitivity reactions. In intramuscular or subcutaneous use, the drug should be administered into various sites. In the case of intravenous administration, the preparation should be warmed to body temperature and injected slowly.
Special precautions for persons administering veterinary medicinal product to animals:
In the case of accidental self-injection, immediately seek medical advice and show the package leaflet or the label to the physician.
Pregnancy: Do not use in pregnancy.
Lactation:
The product may be used in lactation.
Interactions with other medicinal products or other forms of interactions: Do not use with urotropine and local anaesthetics from the group of 4-aminobenzoic acid esters. Do not combine with acetylsalicylic acid. Sulphonamides may transport drugs strongly binding with proteins, such as methotrexate, warfarin, phenylbutazone, thiazide diuretics, salicylates or probenecid. Therefore, concentrations of the listed drugs should be monitored. Simultaneous use of myelosuppressive drugs intensifies leucopoenia and thrombocytopenia.
Combining them with hepatotoxic drugs enhances their negative effect on the liver. Since the bacteriostatic effect of sulphonamides may interfere with the bactericidal effect of penicillins, their simultaneous application is not recommended.
Overdose (symptoms, procedures concerning immediate help and antidotes): Overdosing the drug causes circulatory insufficiency and the occurrence of nervous system symptoms such as motor ataxia or significant apathy. A coma occurs in acute poisonings. In cattle, acute poisoning may be indicated by shock symptoms, characterised by muscle tremor, muscle paralysis and vision impairment. Overdosing sulphonamides may lead to 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.

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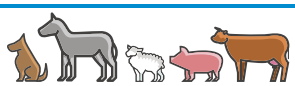
Polisulfamid®

PRODUCT FOR USE IN BACTERIAL INFECTIONS

Solution for injection for horses, cattle, swine, sheep and dogs



In dogs, overdosing the drug may result in thymus hyperplasia or hypothyroidism. In the case of overdose, symptomatic treatment should be applied.

Pharmaceutical incompatibilities:

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

Available containers 250 ml

Shelf life 3 years

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

Marketing authorisation 789/99

2016-04-08 SPC

Marketing authorisation holder

Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
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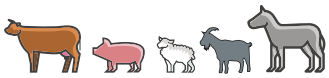
Rehydrat®

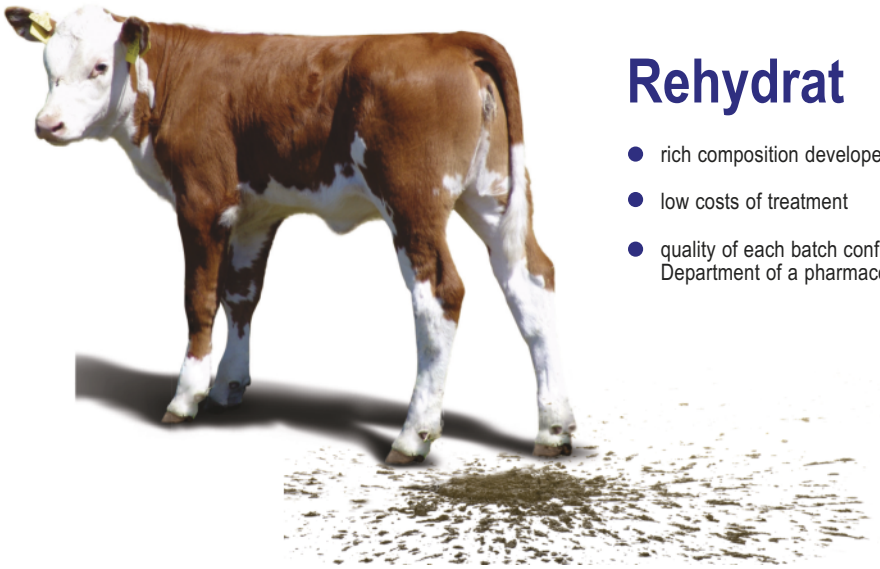
PRODUCT SUPPLEMENTING ELECTROLYTES

Dietetic feeding stuff for calves, piglets, lambs, kids and foals



Ingredients
Glucose – 74.31 g/100 g (source of carbohydrates)
Sodium chloride – 11.87 g/100 g
Sodium bicarbonat – 8.48 g/100 g
Potassium chloride – 5.09 g/100 g (26 700 mg of potassium [K] / kg)
Total chloride content – 9.62 g/100 g (96 200 mg/kg)
NUTRITIONAL ADDITIVE
Zinc sulfate heptahydrate – 0.25 g/100g (570 mg of zinc [Zn] / kg)
(3b trace element, E6 Zinc-Zn)
Analytical constituents:
Per 100 g of Rehydrat, Sodium 7.0 g

Do not waste your time on diarrhoea



Rehydrat

- rich composition developed by best specialists
- low costs of treatment
- quality of each batch confirmed by the Quality Control Department of a pharmaceutical company

Indications
In case of risk, during or following periods of disturbed digestion (diarrhea).
Directions for use
Dissolve sachet containing 280g of the product in 10 litres of water.
Apply 0.5 to 1 litre of the solution per 10 kg of body weight a day. The dose should be given in 2 to 5 portions over 24 hours.
Use for 1 to 7 days, or 1 to 3 days if this is the only possible method to feed the animal.
Consult a veterinarian before use.
Storage
Store in a dry dark place, at a temperature not exceeding 25°C, in the original package, tightly closed.
Available container 280 g
Shelf life 1 year
For animal treatment only
Biowet Puławy Sp. z o.o. identification number: αPL0614003p
Date of development of the leaflet - 06.03.2017 r.

Marketing authorisation holder
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Biowet PUŁAWY

Rehydrat® C NOVELTY

PRODUCT SUPPLEMENTING ELECTROLYTES TO BE USED IN DANGER OF DEHYDRATION

Dietary compound feed for calves, lambs, kids and colts

Composition per 100 g

Dextrose monohydrate (source of carbohydrates)	40.0 g
Blonde plantain (*Plantago ovata)*	27.0 g
Dry 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 L-glutamine 0.2 g (2 000 mg /kg)

Vitamins

Niacin (niacinamide) 0.8 g (8 000 mg /kg)

Vitamin E (alpha tocopherol acetate) 0.2 g (2 000 mg /kg)

Analytical composition

Sodium 4.0%, potassium 1.8%, chlorides 8.5%

Electrolytes for calves, lambs, kid goats and foals

Rehydrat C

- ensures proper hydration
- improves peristalsis
- stimulates restoration and growth of bowel cells
- regulates intestinal flora

Properties and indications

Use in animals at risk of dehydration, during periods of and recovery from digestive disorders (diarrhoea). *Plantago ovata* contained in the product protects intestinal mucosa, whereas glutamine stimulates reconstruction and growth of intestinal cells.

Directions for use

Seek advice of a veterinarian before use.

Preparation of the solution:

Calves and colts

Mix 100 g of the product (1 sachet) with 2 litres of water or milk having temperature of 40°C.

Lambs and kids

Mix 25 g of the product (1/4 sachet) with 0.5 litre of water or milk having temperature of 40°C.

Administer the mixture within the maximum of 20 minutes after preparation, before the product turns into gel.

It is recommended to administer the solution every 12 hours,

– from 1 to 7 days

– from 1 to 3 days, if this is the only feeding method.

Animals must be provided with 24/7 access to fresh water.

Storage

Store in a dry and dark place at room temperature, in the original package.

Package size

Cardboard box containing 10 sachets x 100 g

Shelf life: 1 year.

Biowet Puławy Sp. z o.o. ref. no.: αPL0614003p

2019-02-15

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
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Salmovir

VACCINE AGAINST SALMONELLOSIS AND PARAMYXOVIROSIS OF PIGEONS

Emulsion for injection for pigeons

Active substances and excipients content
1 dose of the vaccine (0.2 ml) contains: inactivated PMV-1 (La Sota strain) no less than 1 Elisa unit,
Inactivated Salmonella cells *(S. typhi, S. paratyphi A, S. paratyphi C, S. typhimurium var. Copenhagen, S. anatum, S. senftenberg)* cells 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 and paramyxovirosis in pigeons.
The postvaccinal immunity occurs approx. 21 days after revaccination and remains for approximately 12 months.

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 basic vaccination of young pigeons not immunised against salmonellosis and paramyxovirosis includes two injections at a four-week interval. The first vaccination should be performed in the third-fourth week of life and the successive vaccination no later than three weeks before migration. Vaccination of adult pigeons which were immunised with Salmovir many times should be conducted annually 2-3 weeks before mating and exhibitions.

Copacetic immunity

Salmovir

- It is an inactivated vaccine which protects pigeons against two dangerous diseases, such as: salmonellosis and paramyxovirosis
- Safe for young pigeons; birds can be vaccinated since 3-4 weeks of life
- Vaccination includes only two injections at a 4-week interval
- Small dose volume: only 0.2 mL of vaccine

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.

Adverse effects
Rarely reported adverse effects are temporary lack of appetite and apathy occurring within several hours after administration of the product 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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Contraindications
Do not use in weak, verminous and sick birds. Do not use in moulting of pigeons.

Withdrawal period Zero days.

Special precautions for storage
Keep out of the reach and sight of children. Store in a refrigerator (2-8°C). Do not freeze. Protect from light. The content of the immediate container should be used within 10 hours after opening.

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Biowet PUŁAWY

Emulsion for injection for pigeons

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 warnings per target species: Only vaccinate healthy animals.

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.

Laying period: The vaccine should not be used during the laying period.

Interactions with other medicinal products or other types of interactions:

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 reactions.

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.

Size of the container 20 doses, 50 doses, 100 doses.

Shelf life 18 months.

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

Marketing authorisation 202/95

SPC 2015.06.23

Marketing authorisation holder
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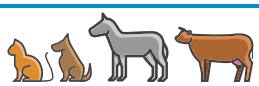
Sedazin

SEDATIVE AND ANALGESIC AGENT
AND MUSCLE RELAXANT

Solution for injections
Xylazine 20 mg/ml



Active substance 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.

Amount to be administered per species, method and route of administration
Routes of administration: intramuscular, intravenous and subcutaneous administration.

Cattle	intramuscularly 0.25–1.5 ml/100 kg b.w. (i.e. 5-30 mg of xylazine/100 kg b.w.) intravenously 0.08 – 0.5 ml/100 kg b.w. (i.e. 1.6-10 mg of xylazine/100 kg b.w.)
Horses	intramuscularly 7.5–15 ml/100 kg b.w. (i.e. 150-300 mg of xylazine/100 kg b.w.) intravenously 3-5 ml/100 kg b.w. (i.e. 60-100 mg of xylazine/100 kg b.w.)
Dogs	intramuscularly, subcutaneously, or intravenously 0.15 ml/kg b.w. (i.e. 3 mg of 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.

Causes anaesthesia and sedation

Sedazin

- relaxes and eliminates sensation of pain
- facilitates examination of excitable animals and application of medicines
- used for myorelaxation and as premedication

Instructions for use None

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

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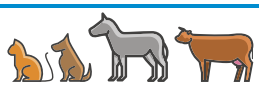
Biowet PUŁAWY

Sedazin

SEDATIVE AND ANALGESIC AGENT
AND MUSCLE RELAXANT

Solution for injections
Xylazine 20 mg/ml



Withdrawal period
Cattle and horses: edible tissues – zero days, milk – zero days. Dogs and cats – not applicable.

Special precautions for storage and warnings
Store at a temperature below 25°C. Protect from light. Do not freeze. Keep out of the reach and sight of children. Do not use after the expiry date stated on the label. Shelf life after the first opening of the direct container – 28 days.

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, life-threatening 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.

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 α_2-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.

Containers 20 ml, 50 ml.

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

Shelf life: 2 years
Marketing authorisation 219/96
2013-01-09 SPC

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BIOWET Biowet PUŁAWY

Streptovac

VACCINE AGAINST PORCINE STREPTOCOCCOSIS

Emulsion for injection for pigs

Quantitative and qualitative composition of active substances
Inactivated *Streptococcus suis* antigens:
serotype 2, concentration before inactivation min. 8.5 x 10^8 CFU/dose,
serotype 1/2, concentration before inactivation min. 8.5 x 10^8 CFU/dose.

Therapeutic indications
Passive immunisation of piglets through active immunisation of pregnant sows and active immunisation of piglets to reduce mortality, clinical symptoms and/or pathological lesions induces by *Streptococcus suis*.
Immunity occurs within two weeks after the vaccination. The degree of immunity largely depends on proper nutrition and zoohygienic conditions.

Amount to be administered per species, method and route of administration
The preparation is administered twice at an interval of 2 – 3 weeks in the dose of 2 ml. The preparation is administered to piglets directly before weaning and 2 – 3 weeks later in the dose of 2 ml in an intramuscular injection in the area of the neck.
Pregnant sows are immunised 5 and 2 weeks before labour.

Do not create problems with immunity

Streptovac

- safe method of protection against streptococcosis
- eliminates *Streptococci* from pigsty premises
- after vaccination, antibodies are passed on to the offspring with colostrum
- effective, safe and economical

Indications for proper administration
Before vaccinations, place the preparation ought in room temperature and thoroughly shake the content of the bottle directly before an injection. Sterile needles and syringes should be used for vaccinations. During the vaccination, shaking the content of the container regularly is recommended. The vaccination procedure should be scheduled in such a way as to use the whole content of the container in one day.

Contraindications Do not use in sick animals.

Adverse reactions
Several hours after administration of the preparation, an increase in the internal body temperature by 2°C may occur. The temperature returns to the normal value without treatment. An inflammatory reaction 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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Withdrawal period Zero days.

Special precautions for storage and transport
Keep out of the reach and sight of children. Store in a refrigerator (+2 to +8°C). Protect from light. Do not freeze. Do not use after the expiry date stated on the label. Shelf life after the first opening of the direct container is one day.

Special warnings and precautions
In the case of accidental self-injection, immediately seek medical advice and show the package leaflet or the label to the physician.
Safety of the veterinary medicinal product used in pregnancy and lactation was not determined. There is no available information concerning safety and efficiency of the vaccine used in combination with other medicinal veterinary products. The decision to use this vaccine before or after administration of another medicinal veterinary product should be considered individually. Since no studies of the inconformity 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.

Packaging 100 ml.

Shelf life 1 year

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

Marketing authorisation 1709/06
2011-10-19 SPC

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Biowet PUŁAWY

Suiferrin

Injection preparation with iron dextran for swine and cattle
Solution for injection
Iron (III) dextran complex 100 mg/ml

Active substance and excipient content 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.

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.

Suiferrin

- **ABSORBABLE** - contains polysaccharide complexes
- **SAFE** - without free iron ions
- **EFFECTIVE** - quicker growth of piglets
- **ECONOMICAL** - competitive price

Indications for proper administration None.
Withdrawal period Meat and offal: zero days.

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

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 oliguria or anuria.

Marketing authorisation holder
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e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Suiferrin

Injection preparation with iron dextran for swine and cattle

Solution for injection

Iron (III) dextran complex 100 mg/ml

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.

Available containers 100 ml, 250 ml.

Shelf life 3 years.

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

Marketing authorisation 2087/11

2017-03-23 SPC

Marketing authorisation holder
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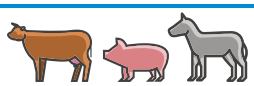
e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Sultrim

Solution for injection for cattle, horses, and swine
Sulfadoxine 200 mg/ml, trimethoprim 40 mg/ml



Qualitative and quantitative composition

Active substance:
Sulfadoxine 200 mg/ml
Trimethoprim 40 mg/ml

Therapeutic indications

Cattle:
bacterial pneumonia in calves caused by *Pasteurella multocida, Mannheimia haemolitica, Corynebacterium pyogenes, Staphylococcus* spp., *Streptococcus* spp.;
bacterial enteritis in calves caused by *Salmonella* spp., *Proteus* spp.;
colibacillosis in calves caused by *Escherichia coli;*
uterine infections in cattle caused by *Staphylococcus* spp., *Streptococcus* spp., *Escherichia coli, Haemophilus somnus, Corynebacterium pyogenes, Pseudomonas* spp.;
listeriosis caused by *Listeria monocytogenes;*
pododermatitis superinfected with *Fusobacterium necrophorum, Bacteroides melaninogenicus,* and *Actinomyces pyogenes.*
Horses:
respiratory tract infections caused by *Staphylococcus* spp., *Streptococcus* spp., *Actinobacillus equi, Rhodococcus equi, Pasteurella* spp.;
gastro-intestinal infections caused by *Rhodococcus equi, Actinobacillus equi, Salmonella* spp.
Swine:
bacterial pneumonia caused by *Streptococcus suis, Actinobacillus pleuropneumoniae, Actinobacillus suis, Bordatella bronchiseptica, Haemophilus parasuis, Pasteurella multocida;*
bacterial arthritis caused by *Arcanobacterium pyogenes, Escherichia coli, Staphylococcus* spp., *Streptococcus* spp.
colibacillosis in piglets caused by *Escherichia coli;*
bacterial enteritis in piglets caused by *Salmonella choleraesuis;*
uterine infections in sows, MMA syndrome caused by *Staphylococcus* spp., *Streptococcus* spp.,*Escherichia coli, Klebsiella* spp.
atrophic rhinitis caused by *Bordetella bronchiseptica*, *Mannheimia haemolytica* and *Pasteurella multocida*.

Contraindications

Do not use in the case of hypersensitivity to the active substances or to any excipient. Do not use in animals with kidney and/or liver failure. Do not use during pregnancy.Do not use in animals with blood dyscrasia (blood components disorder). Do not use in dehydrated animals.

Increased effect of active substances

Sultrim

- **SULFONAMIDES** have a bacteriostatic effect. They reduce the amount of produced toxins. They lower bacterial virulence.
- TRIMETHOPRIM - its antimicrobial effect involves inhibition of bacterial reductases participating in the conversion of folic acid in its active form (tetrahydrofolate).
- Combined effect of SULFADOXINE and TRIMETHOPRIM involves a double block of folic acid synthesis, resulting in the inhibition of the synthesis of purines, and ultimately of deoxyribonucleic acid.

Posology and routes of administration

Horses, cattle, swine: 13.33 mg/kg b.w., i.e. 1 ml/15 kg b.w. intravenously, intramuscularly or subcutaneously, once per day for 4-6 days.

Recommendations for proper administration

In intravenous administration, the product should be injected very slowly and the animal's breath and heart rate, as well as the colour of the conjunctiva, should be monitored.

Adverse reactions

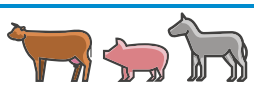
After intramuscular or intravenous injection painful swelling might occur at the injection site, which will disappear spontaneously. Hypersensitivity to the drug has been reported, especially after rapid intravenous administration.
Kidney dysfunction has been reported, caused by sulphonamide precipitation in renal tubules, especially in dehydrated animals, in animals with acidemia, or after administration of high doses of the medicine.
Any adverse reactions which emerged after administration of this product or any observed symptoms not listed in the leaflet (including symptoms 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.

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Solution for injection for cattle, horses, and swine

Sulfadoxine 200 mg/ml, trimethoprim 40 mg/ml



The report form should be downloaded from http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Withdrawal time

Meat and offal:

Cattle, horses, swine:

intravenous administration – 6 days, intramuscular administration up to 4 ml –15 days

intramuscular or subcutaneous administration over 4 ml – 30 days

Milk: Cattle: 4 days

Special precautions for storage and transportation

Keep out of the reach and sight 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 the expiry date indicated on the label and the package. Expiration date refers to the last day of the month.

The Period after Opening of the primary container: 28 days

Special warnings and precautions

Special warnings concerning each of the target animal species

In horses treated with detomidine administration of the drug may cause severe arrhythmia.

Special precautions for use in animals

Large doses of the drug should be administered intravenously. In intravenous administration, the medicine should be injected slowly. The maximum dose given in one injection site in intramuscular or subcutaneous administration should not exceed 20 ml. The product usage should be based on susceptibility tests results and local regulations on sulphonamides application. Administration of an insufficient dose or too short treatment may lead to the development of drug resistance. Sulphonamides in combination with trimethoprim, especially after prolonged treatment, might cause a deficiency of folic acid and vitamins produced by gastrointestinal microbiota.

Special precautions for persons administering the veterinary medicinal product to animals

The medicine should be administered slowly to avoid accidental self-injection. Wash your hands after usage. In case of contact with eyes or skin, the contact site should be flushed with plenty of water. In case of accidental self-injection, professional assistance should be sought immediately and the leaflet or the package should be shown to the physician. People with diagnosed hypersensitivity to sulfadoxine or trimethoprim should avoid contact with the veterinary medicinal product or use it with caution. The product should not be administered by pregnant women.

Pregnancy Do not use during pregnancy.

Lactation The product can be used during lactation.

Interaction with other medicinal products and other forms of interaction

Do not combine 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, might increase the risk of sulphonamides precipitation in the urinary system. Trimethoprim might increase the effectiveness of antithrombotic agents, such as warfarin, by inhibiting its metabolism.

Overdose (symptoms, immediate aid procedure, and antidotes)

Overdosing the medicine in newborn animals and individuals with decreased liver and/or kidney functions may result in the accumulation of the drug and its metabolites.

Pharmaceutical incompatibilities None reported.

Special precautions for the disposal of the 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 a veterinarian to learn about ways of disposal of no longer required medicines. These measures will help to protect the environment.

Available containers 100 ml

Shelf life 2 years.

For animal treatment only. Subject to a medical prescription – a prescription drug. To be administered under the supervision of a veterinarian.

Marketing authorisation 272g/17

2018-04-03 SPC

Marketing authorisation holder

Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,

e-mail: sekretariat@biowet.pl, www.biowet.pl

Testoket

TEST FOR DETECTING KETONE BODIES
IN COW URINE OR MILK

Rapid test for detecting ketone bodies in the cow's urine or milk
Sulfadoxine 200 mg/ml, trimethoprim 40 mg/ml

Ingredients
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.

Easy diagnosis of ketosis in cows

Testoket

- detection of ketone bodies in urine or milk
- easy test procedure
- quick test result

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.
Pack content 10 x 1g
Storage Store at below 25°C. Protect from light.
Shelf life 18 months.
Warnings
Do not freeze! Keep out of the reach and sight of children.
For veterinary use. For individual use by animal owners. For animal treatment only.
PL/WR 000045
2013-10-25

Marketing authorisation holder
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Biowet PUŁAWY

Tiamfenikol
Biowet Puławy

Solution for injections for cattle

Tiamfenikol 250 mg/ml

Active substance and excipient content 1 ml contains:
Active substance: thiamphenicol 250 mg
Excipient: propylene glycol 100 mg

Therapeutic indications
The product is intended for treatment of:
- diseases of the respiratory tract caused by caused by *Bordetella bronchiseptica, Haemophilus spp., Klebsiella spp., Pasteurella spp.,*
- diseases of the gastrointestinal tract caused by *Escherichia coli, Salmonella spp.*
- endometritis caused by *Staphylococcus spp., Streptococcus spp., Listeria monocytogenes, Brucella spp., Haemophilus spp., Escherichia coli,*
- injuries infected by *Staphylococcus spp., Streptococcus spp., Proteus spp.*

Respite in fighting bacteria

Tiamfenikol Biowet Puławy

- has a broad-spectrum effect on Gram-negative and Gram-positive bacteria, especially anaerobic bacteria
- works quickly
- is perfectly absorbed
- effectively treats diseases of the respiratory and gastrointestinal systems, metritis and infected wounds in cattle
- short withdrawal period for milk – 48 hours

Posology for each species, route and method of administration
Administer the product intramuscularly in the following doses:
25 – 50 mg of thiamphenicol/kg b.w./day.
The drug should be sued in two divided doses every 12 hours using 1-2 ml/20 kg b.w. The duration of treatment ranges from 3 to 7 days.

Recommendations for proper administration
None.

Contraindications
Do not use in the case of hypersensitivity to thiamphenicol.
Do not administer in combination with β -lactam antibiotics.

Adverse reactions
Rarely, in the long-lasting use of high doses of the drug, a skin rash and a decrease in the level of haemoglobin and erythrocytes might occur. Benign pain that disappears spontaneously may sporadically occur at the injection site.
Using the drug longer than the recommended time might be conducive to development of fungal infections.
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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Withdrawal period
Edible tissues – 8 days. Milk – 48 hours.

Marketing authorisation holder
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Solution for injections for cattle

Tiamfenikol 250 mg/ml

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 durability period after the first opening of the immediate container – 28 days.

Special warnings

Special warnings concerning each of the target animal species:

Particular caution should be taken when using the product in animals with advanced renal insufficiency or in animals with inflammatory and degenerative lesions of the liver.

Special precautions for use in animals:

The product should be used on the basis of results of resistance tests for bacteria isolated from sick animals. If this is impossible, treatment should be performed on the basis of local epidemiological information concerning sensitivity of isolated bacteria.

Special precautions for persons administering the medicinal veterinary product to animals:

In the case of an accidental self-injection, seek medical help and give the leaflet or the packaging to the doctor. After an accidental contact with skin or mucosa, immediately wash the sites with water.

Pregnancy: Do not use in pregnancy.

Lactation: Administering the product in lactation, observe the 48-hour waiting period for milk.

Interaction with other medicinal products and other forms of interaction

The product has a synergic effect in combination with oxytetracycline and macrolides.

The product should not be combined with β -lactam antibiotics.

Overdose (symptoms, procedures concerning immediate help and antidotes):

Toxicity tests were performed on rats in which the lethal dose is 10g/kg b.w. in oral administration. It was not determined for ruminants.

No toxic effect of the drug was observed in cattle after higher than the recommended doses (up to 60 mg/kg b.w.) had been applied.

Pharmaceutical incompatibilities:

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.

Available containers 100 ml.

Shelf life 2 years

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

Marketing authorisation 1550/04

2015-04-15 SPC

Marketing authorisation holder

Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,
e-mail: sekretariat@biowet.pl, www.biowet.pl

Vecort ®

GLUCOCORTICOSTEROID PRODUCT

Injection solution for dogs, cats and foxes
Flumetazon 0,5 mg/ml

Active substance
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.

Vecort®
Flumetazon - glucocorticosteroid with strong effect
• antiinflammatory • antiallergic • antiexudative • analgesic

Back in veterinary clinics!

Vecort

- Flumetazon (6-9-difluoro-16 methylprednisolone) is a chemically modified prednisolone and shows stronger antiinflammatory and gluconeogenic effect.
- It may be administered i.m., s.c., i.v. and intra-articularly.
- Vecort -1 injection = 3 days of effect

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.
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

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BIOWET Biowet PUŁAWY

Injection solution for dogs, cats and foxes

Flumetazon 0,5 mg/ml

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, 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 http://www.urpl.gov.pl (Veterinary Medicinal Products Division).

Withdrawal period Not applicable.

Special precautions for 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

Special warnings for each target species:

Caution should be exercised when using the product in animals with heart failure, diabetes and chronic renal failure.

Special precautions for persons administering the veterinary medicinal product to animals: 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.

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 for 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.

Available containers:

A single 20 ml clear glass bottle, packed individually in a cardboard box.

Shelf life 2 years

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

Marketing authorisation 951/99

2017-10-24 SPC

Marketing authorisation holder

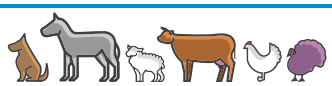
Biowet Puławy Ltd, H. Arciucha 2 str., 24-100 Puławy, Poland,

e-mail: sekretariat@biowet.pl, www.biowet.pl

Vitaminum B_1
Biowet Puławy

PRODUCT SUPPLEMENTING DEFICITS OF VITAMIN B_1

Solution for injections
Thiamine hydrochloride – 25 mg



Active substance and excipient content 1 ml contains:
Active substance: thiamine hydrochloride – 25 mg.
Excipient: phenol – 2.25 mg.

Therapeutic indications
Hypovitaminosis and avitaminosis B_1:
- in carnivorous animals that are on a diet rich in raw fish,
- in animals artificially fed with glucose infusions,
- in 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, osteoarthritis, nervous distemper, muscle weakness and digestive disorders leading to deficiency of vitamin B.
- chickens, turkeys: ataxia, spasms, paralysis, muscle atrophy, polyneuritis.

Posology for each species, routes and methods of administration
Use intravenously 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.

Recommendations for proper administration
The product should not be administered intravenously as this might cause an anaphylactic shock.
In order to properly administer the product, instructions in this leaflet should be followed.

Contraindications
Do not use in the case of hypersensitivity to the active substance or the excipient.

Adverse reactions
Acute pain resulting from the irritating effect of thiamine might occur during administration of the drug (particularly in dogs).
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 http://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Withdrawal period
Meat and offal: cattle, sheep, horses, chickens, turkeys – zero days
Eggs: turkeys – zero days
Milk: cattle – zero days, sheep – zero days, Dogs – 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. Store in the closed container.

Special warnings
Special warnings concerning each of the target animal species: None
Special precautions for use in animals:
The product should not be administered intravenously as this might cause an anaphylactic shock.
Special precautions for persons administering the medicinal veterinary product to animals:
After accidental contact of the drug with the eye, the drug might have an irritating effect resulting in dacryorrhea. In this case, rinse the eye with plenty of lukewarm water or saline immediately. Particular caution should be taken to avoid self-injection during administration. In the case of self-injection, especially intravenously, an anaphylactic shock, impaired respiration and temporary hypotension might occur.
Pregnancy: The product can be used in pregnancy.
Lactation: The product can be used in lactation.
Laying period: The product can be used in the laying period.

Interaction with other medicinal products and other forms of interaction
Administration of amprolium (particularly in turkeys) may cause thiamine deficiency.
The product should not be combined with iron solutions.
Avoid administering the drug in combination with plants with a large content of thiaminase as its excess causes decomposition of vitamin B.

Overdose (symptoms, procedures concerning immediate help and antidotes):
Acute poisonings occur in animals only when the recommended dose is exceeded many times. Convulsions, cyanosis, breathing difficulties and lower blood pressure occur. Symptoms of chronic poisoning do not occur as vitamin B_1 is well soluble in water and is not accumulated in the body because its excess is excreted in urine. Thiamine overdose effects are not observed in clinical practice. Even if the recommended doses are exceeded, no medical intervention is necessary.

Pharmaceutical incompatibilities:
Sulphites found in drinking water may cause decomposition of vitamin B_1. The product should not be administered with neutral or alkaline solutions as these might cause decomposition of thiamine. Since no conformity studies of this veterinary medicinal product have been conducted, this product must not be combined with other medicinal veterinary products.

Marketing authorisation holder
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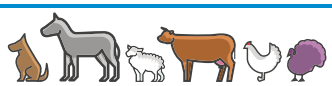
Vitaminum B_1
Biowet Puławy

PRODUCT SUPPLEMENTING DEFICITS OF VITAMIN B_1

Solution for injections
Thiamine hydrochloride – 25 mg



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 50 ml
Shelf life 18 months
For animal treatment only. Subject to medical prescription – prescription drug. To be administered under veterinary supervision.
Marketing authorisation: 969/00
2015-01-28 SPC

Marketing authorisation holder
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Biowet PUŁAWY

Vitaminum C
Biowet Puławy

PRODUCT SUPPLEMENTING DEFICITS OF VITAMIN C

Solution for injections
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.

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 5- 10 mg/kg b.w. i.e. 0.05 – 0.1 ml/kg b.w.
Swine, sheep 8- 16 mg/kg b.w. i.e. 0.08 – 0.16 ml/kg b.w.
Dogs, cats, foxes 10–20 mg/kg b.w. i.e. 0.1 – 0.2 ml/kg b.w.
Administer the product for 5-7 days (administration of ½ dose twice a day is recommended).

Indications for proper administration
When used intravenously, the product should be warmed to body temperature and injected slowly.

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

Withdrawal period
Meat and offal: 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, scorbates 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.
Pharmaceutical incompatibilities:
Ascorbic acid displays chemical incompatibility with sodium bicarbonate, sodium salicylate, sodium nitrate, theobromine, hexamethylenetetramine (methenamine), chlorpromazine hydrochloride, methylprednisolone sodium succinate. 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.

Shelf life 2 years.

Packaging 100 ml orange glass bottles.

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

Marketing authorisation 991/00
2014-12-12 SPC

Marketing authorisation holder
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Biowet PUŁAWY

Read the package leaflet before use of the veterinary medicinal product.

To get more information on a medicinal product,
contact the Marketing Authorization Holder.

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Leaflet date: January 2020

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