Biowet PUŁAWY

Offer
for cattle and pigs

www.biowet.pl

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

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

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

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www.biowet.pl

Date of issue: April 2025

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Active ingredients and products list

Ascorbic acid
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- Calemfos – compound preparation, oral solution
- Calem plus – compound preparation, oral solution
- Calmagluc – compound preparation, injectable solution

Caffeine
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Enrofloxacin
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- Enflocyna 100 mg/ml – injectable solution
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- Calmagluc – injectable solution

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Propylene glycol
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- Injectio Glucosi 40% – injection solution
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- Mlek-test – diagnostic
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- Polisulfamid – compound preparation, injection solution
- Rehydrat – compound preparation, powder
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- Sedazin – injection solution
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- Testoket – diagnostic
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- Enflocyna 50 mg/ml – injection solution
- Injectio Glucosi 40% – injection solution
- Mastiprewent – compound preparation, ointment
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- Calcii borogluconas 25% inj. – injection solution
- Calmagluc – compound preparation, injection solution
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- Enflocyna 50 mg/ml – injection solution
- Enflocyna Sol – oral solution
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- Polisulfamid – compound preparation, injection solution
- Rehydrat – compound preparation, powder
- Rehydrat C – compound preparation, powder
- Vitaminum B_1 Biowet Puławy – injection solution
- Vitaminum C Biowet Puławy – injection solution

Antygen Brucella Abortus do OKAP

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

Intended use
Brucella abortus antigen for OKAP is an in vitro diagnostic product used in veterinary medicine. The preparation is intended for laboratory testing for brucellosis using the acid plate agglutination test.
Composition
Suspension of inactivated *Brucella abortus* strain S-99 cells, stained with Rose Bengal, suspended in lactate buffer with the addition of 0.5% phenol.
Instructions for use
Shake well before use.
Use according to Instruction No. 27/2003 of the Chief Veterinary Officer dated June 25, 2003 (Ref. No. GIW VII.420/lab-4/2003).
Storage conditions
Store at +2°C to +8°C.
Protect from light.
Warnings
Do not freeze.
Keep out of sight and reach of children.
User precautions
In case of contact with eyes or skin, rinse thoroughly with plenty of water.
Package contents
20 ml
For veterinary use only.

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

Antygen Brucella Abortus do OWD

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

Intended use
Brucella Abortus Antigen for CFT is an in vitro diagnostic product used in veterinary medicine. The preparation is intended for laboratory testing to diagnose animal brucellosis using the Complement Fixation Test (CFT) method.
Composition
Suspension of inactivated Brucella abortus strain S-99 in physiological saline.
Instructions for use
Shake well before use.
Use in accordance with Instruction No. 28/2003 of the Chief Veterinary Officer, dated June 25, 2003 (Ref. No. GIW VII.420/lab-5/2003).
Storage conditions
Store at a temperature of +2°C to +8°C.
Protect from light.
Warnings
Do not freeze.
Keep out of sight and reach of children.
User precautions
In case of contact with eyes or skin, rinse thoroughly with plenty of water.
Package contents
10 ml
For veterinary use only
Listed in the register of in vitro diagnostic products of the Chief Veterinary Officer.

Marketing authorization number: PL/WR 000043
SPC: 2016-06-03

Aptovac

Inactivated vaccine for pigs against respiratory infections

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.

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

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

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

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

second vaccination: 3 – 4 weeks prior to farrowing,

repeated vaccination: 3 – 4 weeks prior to next farrowing.

Vaccination plan for facilities with mixed infections caused by *Actinobacillus pleuropneumoniae* and *Pasteurella multocida* reported in weaners and fatteners.

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.

Withdrawal period

Zero days.

Special precautions for storage

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

Special warnings

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

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

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

Pregnancy:

There are no contraindications for using this product during pregnancy.

Interaction with other medicinal products and other forms of interaction:

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

Pharmaceutical incompatibilities:

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

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Pack size: 100 ml

Expiry date: 1 year

For animal treatment only.

Prescription veterinary medicine.

To be administered under veterinary supervision.

Marketing authorisation number: 1263/02

SPC 2014-08-01

Avituberculin

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

Composition

Each ml contains:

Active substance:

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

Excipient: phenol 5 mg

Clear, colourless or straw-yellow solution

Target species

Cattle

Indications for use

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

Contraindications

None

Special warnings

Special warnings:

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

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

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

Do not use the product simultaneously with glucocorticoids.

Special precautions for safe use in the target species:

None

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

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

Pregnancy and lactation:

No adverse effect on pregnancy and lactation was identified.

Due to a higher risk of false negative results, tuberculin testing should not be performed in the period within 2 weeks before and 2 weeks after delivery.

Interaction with other medicinal products and other forms of interaction:

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

Overdose:

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

Major incompatibilities:

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

Adverse events

None reported.

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

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

The product is injected intradermally in a dose of 0.1 ml, which corresponds to 2500 IU of tuberculin.

Advice on correct administration

Tuberculn test procedure

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

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

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

Interpretation

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

Avituberculin

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

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

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

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

Withdrawal period(s)

Meat and offal – zero days.
Milk – zero days.

Special storage precautions

Keep out of the sight and reach of children.
Store in a refrigerator (2°C – 8°C).
Protect from light.
Do not freeze.
Shelf life after first opening the immediate package: 24 hours.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel./Fax: + 48 (81) 886 33 53, Tel.: + 48 (81) 888 91 00
e-mail: sekretariat@biowet.pl
Contact details to report suspected adverse events:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel: + 48 (81) 888 91 33, + 48 509 750 444
e-mail: biowet@biowet.pl

For animal use only.
Prescription veterinary medicine.
To be administered under the supervision of a veterinarian.

Marketing authorisation number: 2627/17
SPC: 2024-12-09

rapid response to ketosis

Boviketozin B_{12}

Product for preventing and supporting the proper treatment of ketosis
(propylene glycol, iodine, cobalt, vitamin B_{12})

- supports proper ketosis treatment and reduces its occurrence frequency
- improves feed intake in animals
- regulates disrupted lactation

Supportive in ketosis and hypoglycemia

Composition per liter

Propylene glycol – 993 ml

Dietary additives / Trace elements per kg

3b305 / Cobalt – 0.9 mg

3b201 / Iodine – 5.0 mg

Dietary additive / Vitamin per kg

3a835 / Vitamin B_{12} (Cyanocobalamin) – 9 mg

Analytical constituents

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

Properties

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

Indications

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

Administration

To be administered during the periparturient period:
Cows – 250 ml once daily from 3 weeks before calving to 6 weeks after calving.
Sheep – 60–100 ml once daily from 6 weeks before lambing to 3 weeks after lambing.
The product should be mixed with water or feed, or administered directly into the mouth.
It is recommended to consult a veterinarian before use.

Storage conditions

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

Shelf life: 2 years
Package size: 1000 ml

Dietary feed mixture for dairy cows and sheep.

Veterinary identification number: αPL0614003p
Leaflet preparation date: 2024-11-19

Bovitrichovac

Inactivated vaccine against bovine dermatophytosis, suspension for injection

Statement of the active substance(s) and other ingredient(s)
Each ml contains:
Inactivated Trichophyton verrucosum strain 43 with concentration of not less than 20%
Yellow to brown suspension with sediment at the bottom, homogeneous after shaking.

Target species
Cattle

Indications for use
Active immunisation of cattle to reduce mortality and clinical signs of ringworm caused by Trichophyton verrucosum.
Therapeutic use of the vaccine in animals with skin affected by cattle ringworm to accelerate the healing process.
Onset of immunity: 3 to 4 weeks after the second injection.
Duration of immunity after 2 injections: 9 to 12 months

Contraindications
None.

Special warnings
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Pregnancy and lactation:
The product can be used during pregnancy and lactation.
Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product, therefore a decision to use this vaccine before or after any other veterinary medicinal product needs to be made on a case-by-case basis.
Overdose:
No side effects other than listed in the adverse events section have been observed after administration of a double dose.
Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events
Cattle

Frequency unknown (cannot be determined based on the available data):	Oedema[1]

[1] Minor restricted oedema emerging at the vaccine injection site, resolving spontaneously within a few days.
Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system:
Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL 02-222 Warsaw, Tel.: +48 22 49 21 687, Fax: +48 22 49 21 605
e-mail: pw@urpl.gov.pl, website: https://smz.ezdrowie.gov.pl

Dosage for each target species, route(s) and method(s) of administration
Intramuscular use.
The vaccine should be administered twice with an interval of 10 to 14 days.
Administer intramuscularly in the gluteal region, according to the following dosage regimen:

Preventively	from 1 week to 4 months of age	5 ml
	from 4 weeks to 8 months of age	5 ml to 6 ml
	8 months of age or older	6 ml to 7 ml
Therapeutically	from 1 week to 4 months of age	7.5 ml
	from 4 weeks to 8 months of age	7.5 ml to 9 ml
	8 months of age or older	9 ml to 10.5 ml

Advice on correct administration
None.

Withdrawal period(s)
Zero days.

Special precautions for storage
Keep out of the sight and reach of children.
Store in a refrigerator (2°C – 8°C). Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after "Exp". The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 14 days.

Special precautions for disposal
Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

Shelf life: 12 months
Available containers: 250 ml

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

Marketing autorisation number: 480/98
SPC: 2025-03-20

Bovituberculin

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

Composition

Each ml contains:

Active substance: Bovine tuberculin, purified protein derivative from *Mycobacterium bovis* strain AN_5 32 500 IU

Excipient: phenol 5mg

Clear, colourless or straw-yellow solution

Indications for use

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

Contraindications

None

Special warnings

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

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

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

Do not use the product simultaneously with glucocorticoids.

Special precautions for safe use in the target species:

None.

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

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

Pregnancy and lactation:

No adverse effect on pregnancy and lactation was identified.

Due to a higher risk of false negative results, tuberculin testing should not be performed in the period within 2 weeks before and 2 weeks after parturition.

Interaction with other medicinal products and other forms of interaction:

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

Overdose:

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

Major incompatibilities:

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

Adverse events

None reported.

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

Al. Jerozolimskie 181C, PL-02-222 Warsaw

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

https://smz.ezdrowie.gov.pl

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

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

Advice on correct administration

Tuberculin test procedure

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

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

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

Bovituberculin

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

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

Interpretation

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

Single tuberculin test – single intradermal injection of bovine tuberculin and interpretation of the reaction:

a). positive reaction (+): if clinical lesions, such as diffuse or extensive oedema, exudation, necrosis, pain or inflammation of lymphatic ducts or lymph nodes in that area are observed or if the increase in skin fold thickness at the injection site is 4.0 mm or greater;

b). inconclusive reaction (+/-): if no clinical signs listed in item a) are observed, and if the increase in skin fold thickness is greater than 2.0 mm but less than 4.0 mm;

c). negative reaction (-): if only limited callous oedema is observed with the increase in skin fold thickness not greater than 2.0 mm, without clinical signs.

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

a). positive reaction (+): a positive reaction to bovine tuberculin which means that the increase in skin thickness is more than 4 mm greater than the reaction to avian tuberculin, or the presence of clinical signs;

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

c). negative reaction (-): a negative reaction to bovine tuberculin, or positive or inconclusive reaction to bovine tuberculin which means that the increase in skin thickness is equal to or less than the reaction to avian tuberculin, and the absence of clinical signs.

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

Withdrawal periods

Meat and offal – zero days.

Milk – zero hours.

Special storage precautions

Keep out of the sight and reach of children.

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

Shelf life after first opening the immediate package: 24 hours.

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

Special precautions for disposal

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

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

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

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel./Fax: + 48 (81) 886 33 53, Tel.: + 48 (81) 888 91 00
e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:

Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel: + 48 (81) 888 91 33, + 48 509 750 444
e-mail: biowet@biowet.pl

Available packaging:

Cardboard box containing 5 vials of 25 doses each.

Shelf life: 2 years

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

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

Brucellognost

Standardized suspension of inactivated
Brucella abortus cells for tube agglutination

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

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

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

Storage conditions
Store at a temperature of +2°C to +8°C.
Protect from light.

Warnings
Do not freeze.
Keep out of sight and reach of children.

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

Package contents: 100 ml
Shelf life: 24 months

For veterinary use.

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

Marketing authorization number: PL/WR 00041
SPC: 2011-04-06

Calcii borogluconas 25% inj.

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

Composition
1 ml contains:
Active substance:
Calcium gluconate 216.6 mg
Excipient:
Chlorocresol 0.9 mg

Therapeutic indications
Treatment of calcium metabolism disorders resulting in hypocalcaemia (parturient paresis in cattle, pregnancy toxaemia in dogs, postpartum hypocalcaemia in swine) and conditions with increased neuromuscular excitability (transit tetany) or with paresis of the motor organs for various reasons (Downer cow syndrome).
As a supportive drug in the treatment of hypomagnesemic tetany, inflammatory and allergic conditions, particularly acute ones and with redness, as well as in cases of swelling and reduced blood oagulation.

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

Adverse reactions
Intravenous administration of high doses of drugs particularly to animals in a general poor condition can result in hypercalcaemia. As a result bradycardia can occur, the strength of the cardiac contractions and frequency of contractions with AV nodal reentrant tachycardia and additional contractions increase. There is an acute myocardial hypoxia, and then muscle shaking, anxiety, sweating, decrease of blood pressure resulting in a collapse.
In order to identify the symptoms of over-dosage at a proper time, the heart beat should be monitored during the infusion.
In intramuscular and subcutaneous injections, and also in peri-intravenous administration some local reactions in a form of transient swelling can occur.
Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from https://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Posology per each species, routes and methods of administration
The product should be administered intravenously or intramuscularly. In dogs it can also be administered subcutaneously.
The size of a dose calculated for 1 kg of the body weight should be varied depending on the nature of a disease and a general health condition of an animal:
– 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.

Withdrawal period
Horse, cattle, pigs:
Edible tissues – zero days,
Milk – zero days,
Dog – not applicable.

Special precautions for storage
Keep out of the sight and reach of children.
Store at a temperature below 25°C. Protect from sunlight. Do not freeze
Do not use this veterinary medicinal product after the expiry date given on the label.
Durability after the first opening of the direct package – 28 days.

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

Calcii borogluconas 25% inj.

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

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

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.

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

Shelf life: 2 years
Available containers: 250 ml.

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

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

Calcigluc

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

Composition

Each ml contains:

Active substances:

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

Excipient:

Phenol 2.6 mg

Clear, colourless or slightly yellow solution.

Target species

Horses, cattle, pigs.

Indications for use

Horses: laminitis, urticaria.

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

Pigs: postparturient hypocalcaemia in sows, rickets.

Contraindications

Do not use in hyperparathyroidism and end-stage renal failure.

Do not use in hypermagnesemia with heart conduction disorders.

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

Special warnings

Special warnings:

Intravenous injection of high product doses, especially in animals in poor health condition, may lead to hypercalcemia.

Special precautions for safe use in the target species:

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

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

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

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

Take special caution to avoid self-injection.

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

Wash hands after use.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

Cardiac glycosides enhance cardiotoxic action of calcium ions. Beta-adrenergic agonists and methylxanthines enhance the effect of calcium ions on the heart. Simultaneous oral administration of tetracyclines increases binding of calcium ions with proteins. Calcium salts administered orally reduce intake of tetracyclines and fluoride compounds (a 3-hour interval is required between administration of these drugs and calcium compounds). Vitamin D, parathormone and acidic pH of feed increase calcium intake, whereas calcitonin, glucocorticoids, excessive amount of lipids, alkaline feed, phytate (e.g. in cereal products), oxalates (e.g. in spinach, rhubarb) and phosphates (milk and milk products) reduce calcium intake.

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

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

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

Overdose:

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

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

Do not administer thiazide diuretics.

Major incompatibilities:

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

Adverse events

Target species: horses, cattle, pigs.

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

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

Calcigluc

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

In case of hypercalcemia, bradycardia is observed, the power of muscle contraction and contraction rate increase, followed by tachycardia and extra contractions. This results in acute myocardial hypoxia, followed by muscle tremor, anxiety, sweats, lowered blood pressure leading to collapse.
Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605, https://smz.ezdrowie.gov.pl.

Dosage for each target species, routes and method of administration
Route of administration: intravenous.
Horses, cattle: 0.5 – 1.0 ml/kg b.w.
Pigs: 2.0 – 5.0 ml/kg b.w.

Advice on correct administration
Inject the veterinary medicinal product slowly at 25-50 ml/min.

Withdrawal period(s)
Horses, cattle, pigs:
Meat and offal – zero days.
Cattle:
Milk – zero hours.

Special storage precautions
Keep out of the sight and reach of children.
Store below 25°C. Protect from light. Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 28 days

Special precautions for disposal
Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Contact details
Marketing authorisation holder and manufacturer responsible for batch release:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel./Fax: + 48 (81) 886 33 53, Tel.: + 48 (81) 888 91 00
e-mail: sekretariat@biowet.pl
Contact details to report suspected adverse events:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel: + 48 (81) 888 91 33, + 48 509 750 444
e-mail: biowet@biowet.pl

Shelf life: 2 years
Package size: 250 ml

For animal use only.
Prescription veterinary medicine.
To be administered exclusively by a veterinarian.

Marketing authorization number: 790/99
SPC: 2024-09-26

compensates for weakness

Calemfos

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

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

Composition
calcium carbonate, propylene glycol, dicalcium phosphate, magnesium chloride
Dietary Additives per kg
3a315 Niacinamide – 103 mg
Technological additives per kg
E 466 Carboxymethylcellulose – 4,538 mg
Analytical constituents (per 595 g)
calcium – 80,325 mg, phosphorus – 9,699 mg, chlorides – 7,438 mg, magnesium – 2,969 mg, sodium – 262 mg, crude ash – 34%, crude protein – <0.5%, crude fiber – <0.3%, crude fat – <1.0%, moisture – 61%

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

Administration
Administer orally: 595 g (1 bottle) 12 hours before calving, then again 6 to 12 hours after calving, and once more 24 hours after calving.
Shake well before use.
Take precautions to prevent aspiration.

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

Shelf Life: 18 months
Package Size: 595 g

Complementary feed mixture for dairy cows.

Veterinary identification number: αPL0614003p
Leaflet preparation date: 2024-11-19

indispensable during the periparturient period

Calem plus

Oral supplement for cows replenishing calcium and magnesium deficiencies

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

Composition
calcium chloride, vegetable oil (refined rapeseed oil), magnesium salt of an organic acid (magnesium citrate), glucose
Technological additives per liter
Polysorbate 80 (E 433) – 5.62 ml
Analytical constituents per kg
calcium – 91.2 g, magnesium – 2.7 g, sodium – 0.01 g, crude protein – <0.5%, crude fiber – <0.3%, crude ash – 29.3%, crude fat – 25.8%, moisture – 40%

Properties and indications
This product is recommended for dairy cows during periods of increased demand for calcium, magnesium, and glucose.
When administered prophylactically during the periparturient period, it prevents a drop in blood calcium levels (hypocalcemia), thereby reducing the risk of postpartum paresis.
The magnesium content enhances calcium utilization, supports neuromuscular function, and contributes to proper heart activity.
Glucose provides an easily absorbed source of energy, reducing the risk of negative energy balance and metabolic disorders.

Administration
Administer orally, 445 ml (1 bottle) approximately 12 hours before calving, then 6 to 12 hours after calving, and again 24 hours after calving.
Shake well before use.
Take precautions to avoid aspiration.

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

Shelf Life: 18 months
Package Size: 445 ml

Complementary feed mixture for dairy cows.

Veterinary identification number: αPL0614003p
Leaflet preparation date: 2024-11-28

Calmagluc

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

Composition

Each ml contains:

Active substance:

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

Excipient:

Phenol 2.6 mg

Clear, colourless or slightly yellow solution.

Indications for use

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

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

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

Contraindications

Hyperparathyroidism and renal failure.

Hypercalcaemia, acidosis.

Hypermagnesemia, Myastenia gravis in dogs, heart conduction disorders.

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

Special warnings

Special warnings:

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

Special precautions for safe use in the target species:

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

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

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

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

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

Take special caution to avoid self-injection.

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

Wash hands after use.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

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

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

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

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

Overdose:

Overdosing the product leads to hypercalcemia and hypermagnesemia, and to increased urinary excretion of calcium and magnesium. Symptoms of hypercalcemia and/or hypermagnesemia may include: nausea, vomiting, polydipsia, polyuria, dehydration and constipation. Long-term overdose leading to hypercalcemia and/or hypermagnesemia may cause vascular and internal organ calcification. In case of overdose, discontinue treatment immediately and replenish fluid deficiency. In case of long-term overdose, use oral and intravenous rehydration with NaCl solutions. Simultaneously (or after rehydration) administer loop diuretics (e.g. Furosemide) in order to increase calcium excretion and prevent the increase in the fluid volume. Do not administer thiazide diuretics. Arrhythmia is a symptom of overdose. When it occurs, discontinue administration of the product.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal

Calmagluc

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

product must not be mixed with other veterinary medicinal products**.**

Adverse events

Target species: horses, cattle, pigs, dogs.

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

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

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

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

Dosage for each target species, routes and method of administration

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

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

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

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

Acute disorders with advanced hypocalcaemia and hypomagnesaemia, such as parturient paresis and tetany caused by hypomagnesaemia – administer a dose of **1.0-1.5 ml/kg bodyweight intravenously or intramuscularly, once, twice and, exceptionally, three times, at 12 hour intervals**.

Diseases not directly related to calcium-magnesium metabolism disorders and as a supplement in inflammations, allergies and toxicity (urticaria, laminitis, oedema, increased neuromuscular excitation) – administer a dose of **0.3-0.5 ml/kg bodyweight, every second day for 6 to 14 days.**

Advice on correct administration

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

Withdrawal period(s)

Dogs – not applicable.

Cattle, horses, pigs – zero days.

Special storage precautions

Keep out of the sight and reach of children.

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

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

Shelf life after first opening the immediate packaging: 28 days

Special precautions for disposal

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

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

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

For animal use only.

Prescription veterinary medicine.

To be administered exclusively by a veterinarian.

Shelf life: 2 years.

Package size: 250 ml.

Marketing authorization number: 1317/02

SPC 2024-09-26

Coffenal

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

Statement of the active substance(s) and other ingredient(s)

Each ml contains:

Active substance:

Caffeine 80 mg

Excipient:

Sodium benzoate (E211) 120 mg

Clear, yellow solution.

Target species

Horse, cattle, pig, sheep, goat, dog, cat

Indications for use

Arrhythmias and circulatory failure during infectious diseases in non-life-threatening conditions.

Contraindications

Do not use in case of acute heart failure and/or myocardial hypoxia.

Special warnings

Special precautions for safe use in the target species:

In animals diagnosed with epilepsy, caffeine should be administered only according to the benefit-risk assessment. In case of symptoms from the central nervous system, immediately discontinue product use and administer antiepileptic drug therapy.

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

Avoid direct contact with the veterinary medicinal product. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Caffeine may endanger the life of humans if consumed in a dose of 5 to 10 g. Acute poisoning has been observed after consumption of caffeine in a dose of 1.0 g (15 mg/kg b.w.)

Pregnancy and lactation:

No information is available on the safety of this veterinary medicinal product when used during pregnancy and lactation in the target species.

Use only according 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-derived products and beta-adrenergic agonists.

If used with methylxanthines and beta-adrenergic agonists (adrenaline, isoprenaline, orciprenaline), enhanced effect of both drug groups on the heart is observed, which is manifested in arrhythmia. Also, the synergy of positive inotropic effect of caffeine and cardiac glycosides has been reported.

Overdose:

Caffeine overdose may lead to tachycardia or tachyarrhythmia, decreased arterial blood pressure, anxiety. Seizures may occur in case of administration of toxic doses. Moreover, overdose of the veterinary medicinal product may lead to muscle stiffness and tremor, increased urine production. In carnivores, vomiting may occur. In case of caffeine overdose, it is recommended to administer pentobarbital sodium.

Major incompatibilities:

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

Adverse events

Horse, cattle, pig, sheep, goat, dog, cat:

Frequency unknown (cannot be determined based on the available data):	Reaction at the administration site[1] Anxiety[2,4], hyperactivity[2,4], vocalizing [2,4] Convulsions[3] Increased heart rate[2,4], arrhythmia[2] Increased respiratory rate[2,4] Gastrointestinal tract disorders[5] Increased creatine phosphokinase activity[4,6]

[1] may occur after subcutaneous injection and is related to the irritating drug effect

[2] may occur after intravenous injection of the product

[3] may occur after intravenous injection of the product in animals diagnosed with epilepsy

[4] may occur in piglets with porcine stress syndrome

[5] may occur as a result of increased gastric glands secretion

[6] may occur within 45 minutes after caffeine administration

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

Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49 21 687, Fax: +48 22 49 21 605

E-mail: pw@urpl.gov.pl, Website: https://smz.ezdrowie.gov.pl

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

Subcutaneous, intramuscular or intravenous use.

This veterinary medicinal product is administered 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 dose size, clinical condition, body weight, route of administration and specific sensitivity of the animal to caffeine should be taken into account.

Coffenal

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

The product takes effect within 15 to 30 minutes after subcutaneous or intramuscular administration, or immediately after intravenous administration. In justified cases, another dose may be administered after 6 to 8 hours.

Advice on correct administration

None.

Withdrawal period(s)

Meat and offal:

Horse, cattle, pig, sheep, goat: zero days

Milk:

Cattle, sheep, goat: zero 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 expiry date which is stated on the label after "Exp". The expiry date refers to the last day of that month.

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

Special precautions for disposal

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

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

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

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:

Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel./Fax: + 48 (81) 886 33 53, Tel: + 48 (81) 888 91 00
e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:

Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel.: + 48 (81) 888 91 33, Tel: +48 509 750 444
e-mail: biowet@biowet.pl

Package size: 50 ml
Shelf life: 2 years

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

Marketing authorization number: 23/94
SPC: 2025-05-07

Enflocyna®

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

Composition

Each ml contains:

Active substance:

Enrofloxacin – 50 mg

Excipient:

Benzyl alcohol E1519 – 15.7 mg

Clear, slightly yellow solution.

Target species

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

Indications for use

Cattle (calves)

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

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

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

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

Sheep

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

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

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

Goats

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

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

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

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

Pigs

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

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

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

Dogs

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

Cats

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

Contraindications

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

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

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

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

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

Special warnings

Special precautions for safe use in the target species:

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

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

Do not use the product to treat less acute infections.

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

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

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

Caution is advised when using enrofloxacin in cats, as doses exceeding the recommended doses may cause retinal degeneration and blindness. In cats below 5 kg body weight, use a dose of 25 mg/ml to avoid overdose.

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

Enflocyna®

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

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

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

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

Pregnant women should avoid contacting the veterinary medicinal product directly.

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

Wash hands after use.

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

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

Pregnancy and lactation:

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

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

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

Interaction with other medicinal products and other forms of interaction:

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

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

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

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

Overdose:

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

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

Cats receiving a dose below 15 mg per kg body weight a day for 21 consecutive days were observed to develop vision disorders. A dose of 30 mg/kg body weight administered once daily for 21 consecutive days led to irreversible damage to sight. A dose of 50 mg/kg body weight administered once daily for 21 consecutive days may cause blindness.

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

No antidote has been identified in case of accidental overdose in these animals, symptomatic treatment should be applied.

Major incompatibilities:

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

Adverse events

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

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

[1] These signs are usually mild and transient.

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

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

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

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

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

Enflocyna®

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

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

Intravenous, subcutaneous or intramuscular administration.

Calves:

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

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

Inject the product slowly, intravenously or subcutaneously.

Do not inject subcutaneously more than 10 ml of the product at one site.

Sheep and goats:

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

Inject subcutaneously.

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

Pigs:

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

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

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

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

Dogs and cats:

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

Inject subcutaneously.

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

Advice on correct administration

In case of multiple injections, rotate injection sites.

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

Withdrawal period(s)

Calves:

Meat and offal after intravenous administration – 5 days.

Meat and offal after subcutaneous administration – 12 days.

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

Sheep:

Meat and offal – 4 days.

Milk – 3 days.

Goats:

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

Pigs:

Meat and offal – 13 days.

Special storage precautions

Keep out of the sight and reach of children.

Store in the original package, in order to protect from light.

Store below 25°C.

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

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

Special precautions for disposal

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

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

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

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Package size: 100 ml
Shelf life: 2 years

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

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

Enflocyna®

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

Composition
Each ml contains:
Active substance:
Enrofloxacin – 100 mg
Excipient:
Benzyl alcohol (E-1519) – 157 mg
Clear, slightly yellow solution.

Indications for use
Cattle
Treatment of respiratory infections caused by *Pasteurella multocida, Mannheimia haemolytica* and *Mycoplasma spp.* susceptible to enrofloxacin.
Treatment of gastrointestinal infections caused by *Escherichia coli* susceptible to enrofloxacin.
Treatment of septicaemia caused by *Escherichia coli* susceptible to enrofloxacin.
Treatment of acute mycoplasma arthritis caused by *Mycoplasma bovis* susceptible to enrofloxacin in cattle less than 2 years of age.
Pigs
Treatment of respiratory infections caused by P*asteurella multocida, Mycoplasma spp.* and *Actinobacillus pleuropneumoniae* susceptible to enrofloxacin.
Treatment of urinary infections caused by *Escherichia coli* susceptible to enrofloxacin.
Treatment of Postpartum Dysgalactia Syndrome – PDS (Metritis Mastitis Agalactia MMA) caused by Escherichia coli and *Klebsiella spp.* susceptible to enrofloxacin.
Treatment of gastrointestinal infections caused by *Escherichia coli* susceptible to enrofloxacin.
Treatment of septicaemia caused by *Escherichia coli* susceptible to enrofloxacin.

Contraindications
Do not use as a preventive measure.
Do not use in case of known cross-resistance to fluoroquinolones or quinolones.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not use in growing horses due to the risk of joint cartilage damage.

Special warnings
Special precautions for safe use in the target species:
Degenerative changes in joint cartilage were observed in calves treated with 30 mg of enrofloxacin per kg body weight, administered per os for 14 days.
Principles of prudent use:
If possible, fluoroquinolones should be used based on results of antimicrobial resistance testing.
During product use, comply with the applicable national and local guidelines for using antimicrobial drugs.
Fluoroquinolones should be used in treating only those diseases in which observed response to administration of other classes of antimicrobial drugs is not satisfactory or the response to treatment is expected to be insufficient.
Using the product contrary to provisions of the Summary of Product Characteristics may lead to increased frequency of microbial resistance to fluoroquinolones and decreased efficacy of treatment using other quinolones due to emergence of a potential cross-resistance.
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. In case of accidental contact with skin or mucous membranes – immediately flush the affected area with water.
People with known hypersensitivity to enrofloxacin should avoid contact with the veterinary medicinal product.
Pregnancy:
Do not use the product during pregnancy.
Lactation:
Do not use the product during the lactation period.
Interaction with other medicinal products and other forms of interaction:
Do not use the product simultaneously with macrolide antibiotics, tetracyclines and theophylline.
Overdose:
Enrofloxacin displays low toxicity after single-dose administration, and low acute toxicity. LD50 is approx. 4000-5000 mg/kg body weight after per os administration in rats and mice, whereas in rabbits which are more susceptible – 500-800 mg/kg body weight.
After a single-dose administration of a particularly high amount, toxic effects may be manifested by lethargy, tremor, tonic seizures, ataxia and dyspnoea.
Use of enrofloxacin doses exceeding 5 mg/kg body weight may cause vision disorders, retinal degeneration and blindness.
Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events
Target species: cattle, pigs

Very rare (< 1 animal/10 000 animals treated, including isolated reports)	Developmental changes in cartilage[1] Gastrointestinal disorders[1] Nervous system disorders [1]

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

Enflocyna®

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

contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products
Al. Jerozolimskie 181C
PL-02-222 Warsaw
Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605
https://smz.ezdrowie.gov.pl

Dosage for each target species, routes and method of administration

Subcutaneous or intramuscular administration.
In case of multiple injections, rotate injection sites.

Cattle

Subcutaneous injection of 5 mg of enrofloxacin per kg of body weight, which corresponds to 1 ml per 20 kg body weight once daily for 3 to 5 days.
In case of acute mycoplasma arthritis caused by Mycoplasma bovis susceptible to enrofloxacin in calves less than 2 years of age: subcutaneous injection of 5 mg of enrofloxacin per kg of body weight, which corresponds to 1 ml per 20 kg body weight once daily for 5 days.
Do not inject subcutaneously more than 5 ml of the product at one site.

Pigs

Intramuscular injection of 2.5 mg of enrofloxacin per kg of body weight, which corresponds to 0.5 ml per 20 kg body weight once daily for 3 days.
In case of gastrointestinal infections or septicaemia caused by Escherichia coli: intramuscular injection of 5 mg of enrofloxacin per kg of body weight, which corresponds to 1 ml per 20 kg body weight once daily for 3 days.
Inject in the neck, near the base of the ear.
Do not inject more than 3 ml of the product at one site.

Advice on correct administration

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

Withdrawal period(s)

Cattle:
Meat and offal: 12 days.
Milk: 4 days.
Pigs:
Meat and offal: 13 days.

Special storage precautions

Keep out of the sight and reach of children.
Store below 25°C. Protect from light. Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate package: 28 days.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Package size: 100 ml
Shelf life: 2 years

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

Marketing authorization number: 715/99
SPC: 2024-09-26

Enflocyna® Sol

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

Composition

Each ml contains:

Active substance:

Enrofloxacin – 50 mg

Excipient:

Benzyl alcohol (E-1519) – 15.7 mg

Clear, slightly yellow solution.

Target species

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

Indications for use

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

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

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

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

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

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

Hens, turkeys: Treatment of infections caused by the following bacteria susceptible to enrofloxacin:

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

Contraindications

Do not use as a preventive measure.

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

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

Do not use in calves with developed forestomach.

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

Special warnings

Special warnings:

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

Special precautions for safe use in the target species:

Principles of prudent use:

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

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

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

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

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

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

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

Pregnancy and lactation:

Do not use during pregnancy and the lactation period.

Laying birds:

The product can be used in the laying period.

Interaction with other medicinal products and other forms of interaction:

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

Overdose:

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

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

Enflocyna® Sol

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

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.
Adverse events
Target species: cattle (calves), pigs, dogs, hens, turkeys, pigeons.

Very rare (<1 animal/10 000 animals treated, including isolated reports)	Developmental changes in cartilage[1] Gastrointestinal disorders [1] Nervous system disorders [1]

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

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

Cattle (calves): 0.05-0.10 ml of the product/kg body weight for 3 to 5 days.
Pigs: 0.05-0.10 ml of the product/kg body weight for 3 to 5 days.
Dogs: 0.05-0.10 ml of the product/kg body weight for 3 to 5 days.
Hens and turkeys: 0.2 ml of the product/kg body weight (corr. to 10 mg of enrofloxacin/kg body weight) daily for 3 to 5 consecutive days.
Administer for 3 to 5 consecutive days; in case of mixed infections or chronic progressive infections, for 5 days. If clinical signs do not alleviate within 2 to 3 days, treatment with alternative antimicrobials should be considered based on the results of susceptibility testing.
Pigeons: 0.1 – 0.4 ml of the product/kg body weight.
Administer the product after dilution in water, assuming that the average daily water intake by 20 pigeons is 1 litre. If the water intake is different, this should be taken into account in dosage.
Salmonellosis: 0.4 ml/kg body weight, corr. to 4 ml/1 litre of water daily for 3 days or 2 ml/1litre for 7 to 10 days.
Mycoplasmosis, respiratory infection in pigeons: 0.2 ml/kg body weight corr. to 2 ml/litre of water for 4 to 7 days.
Other bacterial infections: 0.1 ml/kg body weight, corr. to ml/litre of water for 3 to 4 days.

Advice on correct administration
Prepared solution of the veterinary medicinal product should be used within 24 hours.
Administer the product after dilution in drinking water, milk or milk replacer. Liquids containing the product should be exchanged every 24 hours.
To ensure a correct dosage, body weight should be determined as accurately as possible.
The intake of the prepared solution depends on the clinical condition of the treated animals.
Concentration of the solution should be properly adjusted, in order to obtain a correct dose of the applied antibiotic in the treated animals.

Withdrawal period(s)
Meat and offal:
Calves, pigs: 10 days,
Hens: 7 days,
Turkeys: 13 days,
Dogs – not applicable.
Do not use in pigeons intended for human consumption.
Do not use in laying hens from which eggs are produced for human consumption.
Do not use in young birds reared for laying from which eggs are produced for human consumption within 14 days before the start of the laying period.

Special storage precautions
Keep out of the sight and reach of children.
Store below 25°C. Protect from light. Do not freeze.Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate package: 28 days.
Shelf life after dilution in drinking water, milk or milk replacer: 24 hours.

Special precautions for disposal
Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

Package size: 100 ml
Shelf life: 2 years

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

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

time to heal wounds faster

Hyalsept

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

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

GMP certified quality

EU sourced raw materials

Unique HA structure

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

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

Method of application
For external use only, applied topically to the wound.
Remove Hyalsept from refrigeration before use and allow it to reach room temperature.
Maintain hygiene during application.
After cleansing the wound and removing fur, apply the appropriate amount of the product onto the wound or a sterile dressing using a sterile syringe.

For small wounds
(Up to 2 cm in diameter): Apply approximately 2 ml of Hyalsept directly onto the wound. Then, cover the wound with a sterile dressing.
For medium wounds
(Up to 7 cm in diameter): Apply approximately 5 ml of Hyalsept onto a sterile dressing. Place the gel-soaked dressing onto the wound and cover it with an additional sterile dressing.
For large wounds
(Up to 10 cm in diameter): Apply approximately 8 ml of Hyalsept onto a sterile dressing. Place the gel-soaked dressing onto the wound and cover it with an additional sterile dressing.
If the dressing adheres to the wound, moisten it before removal, e.g., with a saline solution.

Packaging
Glass bottle containing 50 ml of Hyalsept, equipped with a cannula for multiple extractions of the gel, packed in a cardboard box.
Shelf life: 24 months

Leaflet preparation date: 2024-03-22

Injectio Glucosi 40%

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

Active substance and excipient content

Glucosum monohydricum 400 mg/ml

Therapeutic indications

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

Contraindications

- Hyperglycaemia
- Water intoxication
- Hypotonic dehydration and acidosis.

Adverse reactions

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

Administration of glucose as the only fluid might lead to development of hypervolemia, hypoosmia and electrolyte imbalance. Parenteral administration of glucose solutions requires administration of potassium, magnesium and phosphates. Too rapid administration of glucose might cause pulmonary oedema. The product displays an irritating effect and may cause pain at the injection site. Administered into peripheral vessels, it causes local thrombotic and inflammatory lesions. Administration of the product with a temperature lower than body temperature might cause irritation and thrombophlebitis at the injection site. Any adverse reactions emerged after administration of the product or any observed symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from https://www.urpl.gov.pl (Department of Veterinary Medicinal Products).

Posology per each species, routes and methods of administration

Administer the product slowly intramuscularly in the following doses:

Animal species	Glucose in substance	INJECTIO GLUCOSI 40%
Cattle, horses	100,00 – 125,00 g	250,0 – 312,5ml
Sheep, goats, pigs	12,50 – 25,00 g	31,0 – 62,5 ml
Dogs, cats	1,25 – 7,50 g	3,0 – 19,0 ml

Recommendations for proper administration

The solution should be warmed to body temperature before intravenous use.

Recommended glucose administration rate: 0.5 g/1 kg b.w./1 hour.

Once the container is opened, the product cannot be stored and used again. If visually detectable changes in the solution or damage to the package occur, the product should not be used.

Withdrawal period

Dogs, cats – not applicable

Cattle, horses, sheep, swine, goats

Edible tissues – zero days

Milk – zero days.

Special precautions for storage

Keep out of the sight and reach of children.

Do not use after the expiry date given on the label.

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

Durability after the first opening of the immediate package – use the content of the package all at once.

Special warnings

Special precautions for use in animals

During administration of glucose solution, proper infusion rate should be maintained. Too rapid or prolonged administration might cause tissue dehydration and water electrolyte disorders.

In diabetic patients, administer glucose only in the case of 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.
Prescription veterinary medicine.
To be administered under veterinary supervision.

Marketing authorization: 752/99
SPC: 2015-05-07

Injectio Pyralgini Biowet Puławy

Injection solution intended for horses, cattle, pigs and dogs (metamizole sodium 500 mg/ml)

Active substance and excipient content

1 ml contains:

Active substance:

Metamizole sodium 500 mg

Excipient:

Sodium pyrosulphate 0.9 mg

Therapeutic indications

Metamizole sodium displays analgesic, spasmolytic, antipyretic and anti-inflammatory effects.

Indications for the use of the drug:

- Pain relief in colic of various aetiology or in other spastic diseases of the gastrointestinal tract in horses and cattle.
- Equine paralytic myoglobinuria.
- Obstruction of the oesophagus with a foreign body.
- Conditions with fever such as mastitis, MMA (Mastitis Metritis Agalactia) syndrome in swine, swine influenza.
- Acute arthritis, rheumatic conditions of the musculoskeletal system, neuritis, neuralgia, tendinitis and inflammation of tendon sheaths.

Contraindications

- Do not use in cats.
- Do not use in animals with disorders of the haematopoietic system.
- Do not use in animals with renal insufficiency and asthma.
- Do not use in the case of hypersensitivity to the active substance or the excipient.

Adverse reactions

Fast intravenous administration may cause shock.

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

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

The drug should be administered intramuscularly or in a slow intravenous infusion.

In horses whose tissues are intended for human consumption, the drug should only be administered intravenously.

The drug can be administered again after 8 hours.

Posology:

Species	Metamizole sodium dose	Product dose
Horses	20–50 mg/kg b.w.	0,4 - 1,0 ml/10 kg b.w.
Cattle	20–40 mg/kg b.w.	0,4 - 0,8 ml/10 kg b.w.
Pigs	15–50 mg/kg b.w.	0,3 - 1,0 ml/10 kg b.w.
Dogs	20–50 mg/kg b.w.	0,4 - 1,0 ml/10 kg b.w.

Indications for proper administration

In order to properly administer the product, instructions in this leaflet should be followed.

Withdrawal period

Horses:

Edible tissues: 12 days after the intravenous administration.

In horses whose tissues are intended for human consumption, the drug should only be administered intravenously.

Cattle:

Edible tissues: 12 days after the intravenous administration
20 days after the intramuscular administration

Milk: 24 hours

Pigs:

Edible tissues: 12 days after the intravenous administration
20 days after the intramuscular administration

Dogs: not applicable.

Special precautions for storage

Store in the original container in order to protect from light.

Store at a temperature below 25°C.

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

Shelf life after first opening of the immediate container – 28 days.

Special warnings

Special precautions for use in animals:

Do not use subcutaneously – metamizole may irritate the subcutaneous tissue.

Special precautions for people administering veterinary medicinal product to animals:

Caution should be taken to avoid accidental self-injection. In rare cases, metamizole can cause reversible but potentially life-threatening agranulocytosis or other reactions such as skin allergies. Persons with diagnosed hypersensitivity to pyrazolones or aspirin should avoid contact with the product.

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

Pregnancy:

The product can be used in pregnancy.

Lactation:

The product can be used during lactation.

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

Injectio Pyralgini Biowet Puławy

Injection solution intended for horses, cattle, pigs and dogs
(metamizole sodium 500 mg/ml)

no longer required. These measures should help to protect the environment.

Other information

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

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

For animal treatment only.
Prescription veterinary medicine.
To be administered only by a veterinary surgeon.

Marketing authorization number: 201/95
SPC: 2021-10-04

Lydium-KLP™

Injection solution intended for cattle, horses, and pigs
(lysozyme dimer 5 mg/10 ml)

Composition
10 ml of the solution contains:
Active substance: lysozyme dimer 5.0 mg
Preservative: thiomersal 1.0 mg
Transparent, colourless solution.

Indications for use
Horses: To support treatment of bacterial and viral infections, in particular gastrointestinal and respiratory inflammations, as well as skin and outer ear inflammations.
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).

Contraindications
None.

Adverse reactions
None known.
Any adverse reactions emerged after administration of the product or any symptoms not listed in the leaflet (including symptoms reported in humans following exposure to the product) should be reported to the competent veterinarian, Marketing Authorization Holder or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. The report form should be downloaded from
https://www.urpl.gov.pl
(Department of Veterinary Medicinal Products).

Dosage for each species, route and method of administration
Horses:
0.02 mg of lysozyme dimer/kg bodyweight (1 ml of the product/25 kg bodyweight) single intramuscular, subcutaneous or intravenous injection.
During concurrent use with antibiotics, 0.01 mg of lysozyme dimer/kg bodyweight (1 ml of the product/50 kg bodyweight) single intramuscular, subcutaneous or intravenous injection.
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.

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.

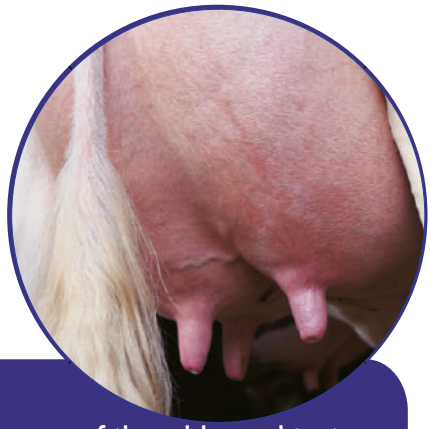
Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products
Medicines should not be disposed of via waste water or household waste. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help protect the environment.

Other information
For further details regarding this veterinary medicinal product, please contact the marketing authorization holder.
Package size: 5 glass bottles in a cardboard box
Shelf life: 4 years

Marketing authorization number: 956/99
SPC: 2019-05-07

Mastiprewent

Udder care ointment for cows and goats
(eucalyptus oil, camphor, menthol, eucerin, yellow petroleum jelly)



- prevents cracking and dryness of the udder and teats
- maintains proper udder elasticity
- spreads easily and provides effective coverage of the udder and teats
- contains plant-derived ingredients: eucalyptus oil, camphor, menthol, eucerin, and petroleum jelly

Composition
Eucalyptus oil, camphor, menthol, eucerine, yellow petroleum jelly.

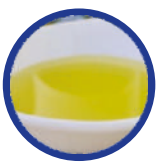
Indications and usage
The product is recommended for the care of udders in cows and goats.
It is applied externally after each milking by coating and then massaging it into the skin of the udder and teats. Regular use ensures proper elasticity and prevents drying and cracking of the udder and teat skin. Due to its properties, it can also be used for inflammatory conditions caused by insect bites, eczema, abrasions, etc.

Contraindications
Avoid direct contact of the product with mucous membranes.

Storage conditions
Store at a temperature not exceeding 25°C.
Protect from light. Keep out of sight and reach of children.

Shelf life: 24 months
Packaging size: 500 g

Leaflet Preparation Date: 2013-10-22



Eucalyptus oil has antiseptic and anti-inflammatory properties

Mentol cools and reduces the sensitivity of pain receptors

Camphor provides antiseptic and warming effects

Mlek-test®

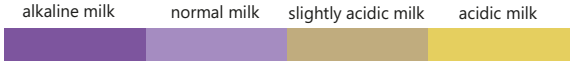
Diagnostic tool for detecting elevated somatic cell counts and assessing the pH of raw milk

- enables evaluation of milk acidity – pH of milk stored in a tank
- helps detect subclinical and clinical udder inflammations
- allows determination of somatic cell count levels starting from 400,000 per 1 ml of milk

Composition
Sodium alkane sulfonate, bromocresol purple, distilled water

Intended use
Mlek-test is an in vitro diagnostic tool used in veterinary medicine. It is designed to test samples of milk taken from animal body to diagnose and control physiological status or pathological conditions.

Directions for use
1. After disposal of the first streams of milk, milk portions of about 2 ml should be squirted onto the tray containing four circular pools. Any excessive milk may be decanted by tipping the tray at an angle of about 50°. Add equal volumes of Mlek-test and the formula and mix thoroughly by swirling the tray. After mixing for about 20 seconds, estimate the degree of thickening and colour change according to the table below.
2. Mlek-test also allows determining approximate acidity of milk stored in tank. To that end, mix equal volumes of milk and the formula on the tray. Check the colour of the mixture with the attached colour scale. The mixture of the formula and milk of proper acidity should become greyish-violet. Any possible acidification of the milk gives a greyish-green to yellow colour (depending on acidity)



RESULT	APPEARANCE OF MIXTURE	CELL COUNT in 1 ml
Negative*	Liquid or tufts and trails vanishing during mixing. Greyish-violet.	Up tp 400 000
Positive*	Jelly-like tufts and trails not vanishing during mixing. Greyish-violet or violet.	Up to 1 000 000
Strongly Positive	Mixture becomes jelly-like mass. Violet or dark violet.	Over 1 000 000

** homogenous liquid mixture during the entire mixing period indicates that the somatic cell count does not exceed 200 000 in 1 ml*

High somatic cell count (positive result) is usually indicative of mastitis.

High somatic cell count in milk for physiological reasons is indicative of oestrus, the colostric period and the dry period.

Storage
Store at below 25° C.

Warnings
Do not freeze!
Keep out of the reach and sight of children.

User precautions
In case of skin or eye contact flush the affected site with profuse amount of water.

Available containers: 500 ml bottles

Shelf life: 18 months

For veterinary use.

Leaflet preparation date: 2013-10-24

Morbital Plus

Injection solution intended for cattle, horses, pigs, dogs and cats
(pentobarbital sodium 400 mg/ml)

Composition

Each ml contains:

Active substance

Pentobarbital sodium 400 mg
(which corresponds to 364.6 mg of pentobarbital)

Excipients:

Qualitative composition of excipent(s) and other constituent(s)	Quantitative composition
Benzyl alcohol (E 1519)	20 mg
Patent Blue V (E 131)	0.01 mg
Ethanol 96%	
Propylene glycol	
Water for injection	

Clear, blue solution.

Target species

Cattle, horses (ponies), pigs, dogs, cats.

Indications for use

Product intended for use in euthanasia of cattle, horses (ponies), pigs, dogs and cats.

Contraindications

Do not use for anaesthesia.

Special warnings

None

Special precautions for safe use in the target species:

Pentobarbital injected intravenously may cause drug induced agitation. To prevent it, administer a proper sedatives before administration of pentobarbital.

Intraperitoneal injection may produce prolonged drug induced agitation; this route of administration may only be used after the animal has been properly sedated.

In order to reduce the risk of agitation, animals should be euthanised in a peaceful environment.

Do not administer the product per os.

Avoid intrasplenic drug administration or injections to organs/tissues with reduced absorption capabilities; this route of administration is only permitted in case of small animals.

Intracardial administration is only possible when the animal has been fully sedated, unconscious or anaesthetized.

Once cardiac and respiratory arrest have been confirmed, monitor the animal for another 10 minutes. In case of finding any signs of life, such as respiration, heartbeat or corneal reflex, it is recommended to re-administer the full or half the recommended product dose.

In case of accidental administration of the product to animals not intended for euthanasia, begin ventilation, administer oxygen and analeptics immediately.

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

Persons with known hypersensitivity to barbiturates and pregnant women should avoid direct contact with the veterinary medicinal product.

Pentobarbital is a potent hypnotic and sedative, therefore it may be toxic for humans once ingested or absorbed through the skin.

Particular caution should be taken to avoid accidental ingestion or self-injection.

In case of accidental self-injection, swallowing, spilling on skin, contact with eyes, seek medical advice immediately and show the package leaflet or the label to the physician.

Immediate medical advice is particularly important in case of self-injection.

In case of spilling on skin, immediately flush the affected area with plenty of water.

In case of contact with eyes, immediately rinse with plenty of water and seek medical advice.

In case of swallowing, rinse mouth and seek medical advice.

In case of contact with the product, do not drive, as sedation is likely to occur.

While administering the product, use impermeable protective gloves.

To the physician:

Pentobarbital concentration in the product is high enough to produce a serious effect on the central nervous system in an adult after accidental self-injection or swallowing of as much as 1 ml. It was found that a dose of 1 g of pentobarbital sodium (which corresponds to 2.5 ml of the product) may be lethal for humans. In case of poisoning on pentobarbital, extend intensive care in order to sustain blood circulation and respiration.

Other precautions:

Consumption of remains of a euthanised animal by other animals may lead to poisoning, sedation or even death. Barbiturates show high stability even at high temperatures. Due to the risk of secondary poisoning, remains of euthanised animals, even after being heat treated, must not be used for feeding to other animals. They should be disposed of in accordance with the local regulations and in a manner preventing access by other animals.

Pregnancy and lactation:

The product can be used in pregnant and lactating animals.

Interaction with other medicinal products and other forms of interaction:

While euthanizing an aggressive animal when intravenous administration is difficult, it is recommended to use premedication with a sedative that is easier to administer (per os, subcutaneously or intramuscularly).

Premedication with sedatives, due to impaired circulation, may delay the expected effect of pentobarbital. This may not be reflected in clinical signs, as agents used for premedication (opioids, agonists of alpha-2 adrenergic receptors, phenothiazines, etc.) by depressing the central nervous system may enhance the pentobarbital performance.

Morbital Plus

Injection solution intended for cattle, horses, pigs, dogs and cats
(pentobarbital sodium 400 mg/ml)

Overdose: Not applicable.
Special restrictions for use and special conditions for use:
None
Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

Minor muscle contractions may be observed in the animal after administration of the veterinary medicinal product. When an intravenous injection is not properly administered into a vein or the product is injected to organs with reduced absorption capabilities, death may be delayed. Barbiturates may produce an irritating effect in case of perivascular administration.
Pentobarbital sodium may cause animal agitation. Premedication/sedation significantly reduces the risk of agitation.
At times, after cardiac arrest, agonal respiration may be observed in the animal. At this stage, the animal is dead in clinical terms.
Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605, https://smz.ezdrowie.gov.pl

Dosage for each target species, routes and method of administration

Dogs, cats, pigs, piglets – administration of Morbital Plus in ml per 1 kg body weight

	Pentobarbital sodium mg/kg m.c.	Morbital plus in mg/kg m.c.	Route(s) and method of administration
Dogs, cats	100-200 mg	0.25-0.5 ml/kg b.w. b.w.	rapid intravenous or intracardial injection
Pigs	100-200 mg	0.25-0.5 ml/kg b.w. b.w.	rapid intravenous injection
Piglets	100-200 mg	0.25-0.5 ml/kg b.w. b.w.	rapid intravenous or intracardial injection

Cattle, horses, ponies – administration of Morbital Plus in ml/100 kg b.w.

Cattle	50 mg	12.5 ml/100kg b.w.	rapid intravenous injection
Horses,	50 mg	12.5 ml/100kg b.w.	rapid intravenous injection

Intravenous injection should be the preferred method of administration. In necessary, before administration of the veterinary medicinal product, a proper sedative should be used. In case of cattle and horses, premedication is compulsory.
In case intravenous administration is problematic, intracardiac injection may be applied only after prior use of deep sedation or anaesthesia.
In small animals, intraperitoneal administration is allowed, but must be preceded by proper sedation.In pets, pentobarbital should be administered at a fixed pace until loss of consciousness is acknowledged.
In horses and cattle, pentobarbital must be administered as a rapid injection.

Advice on correct administration

Do not administer the product with visible signs of deterioration.

Withdrawal period(s)

Not applicable.
Appropriate actions must be taken to ensure that remains of animals this veterinary medicinal product was administered to, as well as animal-by products from these animals will not enter the food chain and will not be destined for consumption by humans or other animals.

Special storage precautions

Store in the original package.
Store below 25°C.

Special precautions for disposal of unused medicinal products or waste materials derived from such medicinal products, if applicable

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

Package size: 100 ml
Shelf life: 2 years

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

Possession and distribution of the product are regulated by laws concerning narcotic drugs or psychotropic substances.

Marketing authorisation number: 3218/22
SPC: 2022-12-08

Oxytan 200

Injection solution intended for cattle, sheep and pigs
(oxytetracycline 200 mg/ml)

Active substance and excipient content

Oxytetracycline – 200 mg/ml (in the form of oxytetracycline dihydrate 216 mg/ml)

Therapeutic indications

The product is intended for use in the treatment of infections induced by microorganisms sensitive to the effect of oxytetracycline, especially in the treatment of:

- atrophic rhinitis induced by *Bordetella bronchiseptica*, *Mannheimia haemolytica* and *Pasteurella multocida,*
- conditions of the umbilicus and joints induced by *Arcanobacterium pyogenes, E. coli* or *Staphylococcus aureus,*
- mastitis induced by *Corynebacterium pyogenes, E. coli, Staphylococcus aureus, Streptococcus agalactiae* or *Streptococcus uberis,*
- endometritis induced by *E. coli* or *Streptococcus pyogenes,*
- pasteurellosis and respiratory infections induced by *Mannheimia haemolytica* and *Pasteurella multocida,*
- septicaemia induced by *Salmonella dublin* and *Streptococcus pyogenes,*
- Erysipeloid of Rosenbach induced by E*rysipelothrix rhisiopathiae.*

Oxytan 200 can also be used to eliminate enzootic abortion in sheep.

Contraindications

Do not use in the case of hypersensitivity to tetracyclines or any component of the product.

Do not use in horses, dogs and cats.

Do not use in animals with renal and hepatic disorders.

Adverse reactions

Sometimes, temporary reactions in the form of pain and/or swelling might occur at the injection site, but they subside spontaneously.

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

Posology for each species, routes and methods of administration

The product should be administered in a single dose, intramuscularly deep into the muscle, in the dose of 20 mg/kg b.w., i.e. 1 ml/10 kg b.w.

The maximum dose administered in one site is as follows:

Cattle:	20 ml
Pigs:	10 ml
Sheep:	5 ml
Piglets:	one day old 0.2 ml
	seven days old 0.3 ml
	14 days old 0.4 ml
	21 days old 0.5 ml
	over 21 days old 1.0 ml/10 kg b.w.

Recommendations for proper administration

In order to ensure that administration is appropriate, the bodyweights of the treated animals should be estimated as accurately as possible. General aseptic rules should be observed during the use of the product. The product should not be diluted before use.

Withdrawal period

Cattle:
Edible tissues – 31 days
Milk – 10 days
Sheep:
Edible tissues – 9 days
Milk – 7 days
Pigs:
Edible tissues – 18 days

Special precautions for storage

Keep out of the reach and sight of children.

Store at a temperature below 25oC. Protect from light. Do not freeze.

Use within 28 days after first opening of the immediate packaging.

Do not use the veterinary medicinal product after the expiry date stated on the label and the box.

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

Special warnings

Special precautions for use in animals:

Pathogen sensitivity to oxytetracycline might be varied. Therefore, use of the product should be based on tests of drug resistance of microorganisms isolated in the given case. If this is impossible, the treatment should be performed on the basis of available local epidemiological information, including official regulations and guidelines.

Improper use of the product might lead to an increased number of oxytetracycline-resistant bacteria and to reduced efficiency of treatment using other tetracyclines as a result of cross-resistance.

In the case of conditions with concomitant impairment of renal functions, the half-life of oxytetracycline is significantly longer and, in the case of multiple administrations, it may accumulate in the body.

If repeated administration of the drug is required, it should not be injected in the area of the body used for the previous injection.

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

People with diagnosed hypersensitivity to tetracyclines should avoid contact with the product. During the use of the veterinary medicinal product, caution should be taken to avoid accidental self-injection and contact with skin and mucosa.

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

Oxytan 200

Injection solution intended for cattle, sheep and pigs
(oxytetracycline 200 mg/ml)

If the product comes into contact with an eye, wash the eye with plenty of water and seek medical advice.
If, as a result of the contact with the product, such symptoms as a rash occur, you should seek immediate medical advice and show the package leaflet or the leaflet to the physician. Swelling of the face, lips or eyes as well as breathing difficulties require immediate medical help.
Pregnancy:
Do not use in pregnancy.
Use of oxytetracycline during bone formation might cause their developmental disorders. Administration of oxytetracycline at the end of pregnancy might cause teeth enamel discoloration.
Lactation:
The product can be used in lactation.
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 dispose of medicines no longer required. These measures should help to protect the environment.

Shelf life
Shelf life for a medicinal veterinary product packed for sale: 2 years.
Available containers: 100 ml

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

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

Marketing authorization number: 2499/15
SPC: 2015-12-01

Oxytocinum Biowet Puławy

Injection solution intended for cattle, horses, pigs, sheep, dogs and cats
(okxytocin 10 j.m./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.

Contraindications

The use of oxytocin is absolutely contraindicated in the following situations:

- obstruction of the reproductive tract (labour with the cervix closed, no full dilation of the cervix, improper position of the foetus/foetuses, etc.),
- occurence of tetanic contractions

Adverse reactions

The effect of high oxytocin doses depends on the functional condition of the uterus and the position of the foetus. Excessive uterine contractions or tetanic contractions induced by oxytocin may lead to exaggerated intensification of labour, metrorrhexis, damage to the foetus or even deaths of unborn foetuses. Intravenous administration of oxytocin for a longer period of time in a large volume of infusion fluid poor in electrolytes may lead to water intoxication of the female. Early symptoms of the intoxication are sadness and depression. Later a coma, convulsions and death of the female may occur. Oxytocin-induced water intoxication requires administration of drugs increasing diuresis.

Failure to observe intervals between successive oxytocin doses (minimum 30 minutes) may lead to excessive uterine contractions.

An allergic reaction may occur in females of all domestic mammals after administration of natural oxytocin instead of the synthetic one.

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

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

The product should be administered in a single intramuscular or subcutaneous injection in the following doses:

cattle, horses: 3-5 ml (which corresponds to 30 – 50 IU),
pigs, sheeps: 2-3 ml (which corresponds to 20 – 30 IU),
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

Withdrawal period

Edible tissues

Cattle, horses, swine, sheep – zero days.

Milk

Cattle, sheep – zero hours

Dogs, cats – not applicable.

Special precautions for storage

Keep out of the reach and sight of children.

Store at a temperature of 2°C – 8°C.

Do not freeze.

Protect from light.

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

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

Special warnings

Special warnings per target species:

Physiological levels of adrenaline significantly reduce the effect of oxytocin on the myometrium and the mammary gland. Therefore, the treated animals should not be distressed in order to achieve complete efficiency.

Special precautions for use in animals:

Metabolic disorders should be eliminated pharmacologically in animals with hypoglycaemia and hypocalcaemia before administration of oxytocin.

Before administration during labour, complete dilation of the cervix must be confirmed.

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

Caution should be taken to avoid accidental self-injection. In the case of accidental self-injection, immediately seek medical advice and show the package leaflet or the label to the physician. Women, especially those breastfeeding and in advanced pregnancy, should avoid contact with the product since oxytocin may induce contractions of smooth muscles (e.g. uterine muscles).

Pregnancy and lactation:

Oxytocin is used to increase uterine contractions during labour and in lactation in order to empty the mammary gland of milk or inflammatory secretion.

Oxytocin is contraindicated in the last stage of pregnancy due to the risk of miscarriage.

Oxytocinum Biowet Puławy

Injection solution intended for cattle, horses, pigs, sheep, dogs and cats
(oxytocin 10 j.m./ml)

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.
Pharmaceutical incompatibilities:
Oxytocin displays pharmaceutical incompatibility with the following substances: warfarin sodium, fibrinolysin, epinephrine bitartrate and prochlorperazine edisylate.
Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products
Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Containers: 50 ml, 100 ml
Shelf life: 2 years

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

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

Marketing authorization number: 45/94
SPC: 2015-01-21

Polisulfamid®

Injection solution intended for horses, cattle, pigs, sheep and dogs
(sodium sulfadimidine 50 mg, sodium sulfacetamide 40 mg, sodium sulfathiazole 30 mg)

Composition

Each ml contains:

Active substances:

Sulfadimidine sodium – 50 mg
Sulfacetamide sodium – 40 mg
Sulfathiazole sodium – 30 mg

Excipient:

chlorocresol – 2 mg
Brown solution.

Target species

Horses, cattle, pigs, sheep, dogs.

Indications for use

Horses:

– respiratory infections caused by *Staphylococcus spp., Streptococcus equi, Pasteurella multocida,*
– gastrointestinal infections caused by *Salmonella spp.,*
– urinary infections caused by *Streptococcus spp., Salmonella spp.,*
– genital tract infections caused by *Streptococcus spp., Escherichia coli, Klebsiella pneumoniae, Salmonella abortus equi,*
– soft tissue infections caused by *Staphylococcus spp., Streptococcus spp.,*

Cattle:

– primary and secondary respiratory infections caused by *Haemophilus somnus, Mannheimia haemolitica, Pasteurella multocida,*
– enzootic pneumonia in calves (BRD) caused by *Mannheimia haemolitica, Pasteurella multocida,*
– colibacillosis in calves caused by *Escherichia coli,*
– calf diphtheria caused by sensitive *Fusobacterium necrophorum,*
– mastitis caused by *Staphylococcus spp., Streptococcus spp., Escherichia coli,*

Sheep:

– respiratory infections caused by *Haemophilus somnus, Mannheimia haemolitica, Pasteurella multocida,*
– enteritis caused by *Escherichia coli,*

Pigs:

– respiratory infections, including atrophic rhinitis in pigs caused by *Streptococcus suis, Actinobacillus pleuropneumoniae, Actinobacillus suis, Bordatella bronchiseptica, Haemophilus parasuis, Pasteurella multocida,*
– gastrointestinal infections caused by *Escherichia coli, Salmonella choleraesuis,*
– genitourinary infections: cystitis, urinary tract infection, MMA syndrome, postpartum infections caused by *Staphylococcus spp., Streptococcus spp., Escherichia coli, Klebsiella spp.,*

Dogs:

– laryngitis, bronchitis and pneumonia caused by *Staphylococcus spp., Streptococcus spp., Bordatella bronchiseptica, Klebsiella spp.,*
– enteritis caused by *Escherichia coli, Salmonella spp.,*
– soft tissue infections caused by *Staphylococcus spp., Streptococcus spp., Proteus spp., Nocardia spp.*

Contraindications

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

Do not use in animals with renal and hepatic failure, haematopoietic disorders, in dehydrated animals or in animals not taking water.

Do not use in pregnant and very young animals.

Special warnings

Special warnings:

Administration of excessively low doses of the product or excessively short therapy leads to development of microbial resistance to sulphonamides. For this reason, results of antimicrobial susceptibility testing must confirm the need of sulphonamide use.

During treatment, animals should be given plenty of water or provided with free access to water to prevent the development of crystalluria.

Sulphonamides are less efficient in purulent drainage and necrotic tissues.

Special precautions for safe use in the target species:

The veterinary medicinal product should be used based on results of microbial resistance for bacteria isolated from diseased animals. If this is impossible, administered treatment should be based on the local epidemiological information concerning susceptibility of isolated bacteria.

After administration of sulphonamides, animals may have difficulty passing urine, cloudy urine or haematuria, therefore they should be closely monitored during treatment.

Animals with hypersensitivity to sulphonamides may develop haematuria or apathy. In that event, discontinue administration of the product.

Dogs are particularly sensitive to sulphonamide action, large breed dogs in particular, in which administration of the product may elicit hypersensitivity reactions.

In case of intramuscular or subcutaneous administration, the product should be injected in a number of different sites.

In case of intravenous injection, the product should be warmed to body temperature and injected slowly.

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

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

Pregnancy:

Do not use during pregnancy.

Lactation:

The product can be used during the lactation period.

Interaction with other medicinal products and other forms of interaction:

Do not use simultaneously with methenamine and local anaesthetics belonging to the group of esters of para aminobenzoic acid.

Do not use simultaneously with acetylsalicylic acid.

Sulphonamides may transport drugs strongly binding with proteins, such as methotrexate, warfarin, phenylbutazone, thiazide diuretics, salicylates or probenecid. Therefore, concentrations of these drugs must be monitored. Using the product simultaneously with myelosuppressive drugs aggravates

Polisulfamid®

Injection solution intended for horses, cattle, pigs, sheep and dogs
(sodium sulfadimidine 50 mg, sodium sulfacetamide 40 mg, sodium sulfathiazole 30 mg)

leucopoenia and thrombocytopenia. Using the product simultaneously with hepatotoxic drugs enhances their negative effect on the liver. Since the bacteriostatic effect of sulphonamides may interfere with the bactericidal effect of penicillin, it is not recommended to use them simultaneously.

Overdose:

Overdose leads to circulatory failure and induces signs of the central nervous system, such as ataxia, significant apathy. Coma may occur in instances of acute poisoning. In cattle, acute poisoning may promote signs of anaphylaxis, manifested in muscle tremor, muscle paralysis and visual impairment.

Overdosing sulphonamides may result in bone marrow damage, aplastic anaemia, granulocytopenia and thrombocytopenia. It may cause hepatitis, icterus, neuritis, degeneration of the spinal cord and peripheral nerves, stomatitis and keratitis.

Overdose in dogs may result in thymic hyperplasia or hypothyroidism.

In case of overdose, administer symptomatic treatment.

Major incompatibilities:

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

Adverse events

Target species: Horses, cattle, pigs, sheep, dogs.

Frequency unknown (cannot be determined on the basis of available data):	• apathy[1], fever[1] • collapse[3], anaphylaxis[1] • difficulty passing urine, cloudy urine, hematuria[1], crystalluria, renal tubular obstruction • swelling at the injection site[2], skin lesions[1], hives (urticaria)[1] • ataxia[3], muscle weakness[3] • arthritis[1] • haemolytic anemia[1], agranulocytosis[1] • blindness[3] • gastrointestinal tract disorders[4]

[1] May occur in animals with hypersensitivity to sulphonamides.

[2] May occur after intramuscular or subcutaneous administration.

[3] May occur in case of rapid intravenous injection.

[4] May occur as a result of bacteriostatic action of sulphonamides on gastrointestinal microbiota. This particularly applies to ruminants in which as a result of bacteriostasis of forestomach microbiota, synthesis of vitamin B may be impaired.

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

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

The veterinary medicinal product should be administered intravenously, intramuscularly, intraperitoneally and subcutaneously.

Dosage: horses, cattle, pigs, sheep, dogs

Therapeutic dose for specific active substance:

sulfadimidine sodium 20-50 mg/kg b.w.

sulfacetamide sodium 16-40 mg/kg b.w.

sulfathiazole sodium 12-30 mg/kg b.w.

i.e. 48-120 mg of total sulphonamides / kg b.w.

Dosage in ml/ kg b.w.:

horses, cattle, pigs, sheep, dogs: 0.4-1.0 ml of the product/kg b.w.

The initial dose should be administered intravenously, which allows to develop high product concentration in the blood.

On consecutive days of treatment, use 2/3 to ½ of the initial dose.

Duration of therapy, with efficacy of the veterinary medicinal product confirmed by antimicrobial susceptibility testing, is 5 to 7 days.

Rapid intravenous injection causes toxic effect, producing clinical signs such as muscle weakness, ataxia, blindness and collapse.

Advice on correct administration

During treatment, animals should be given plenty of water or provided with free access to water to prevent the development of crystalluria.

The veterinary medicinal product administered intramuscularly or subcutaneously should be injected at different sites, whereas in case of intravenous injection, the product should be warmed to body temperature.

When administered intravenously, inject the product slowly.

Withdrawal period(s)

Cattle

Meat and offal – 10 days

Milk – 5 days

Sheep:

Meat and offal – 10 days

Do not use in sheep from which milk is intended for human consumption.

Pigs:

Meat and offal – 10 days

Dogs: not applicable

Do not use in horses from which meat and offal are intended for human consumption.

Horses treated at any time with the veterinary medicinal product must not be intended for slaughter for human consumption.

For use only in horses with signed declaration "not intended for slaughter for human consumption under applicable laws" in the horse passport.

Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C).

Protect from light. Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is

Polisulfamid®

Injection solution intended for horses, cattle, pigs, sheep and dogs
(sodium sulfadimidine 50 mg, sodium sulfacetamide 40 mg, sodium sulfathiazole 30 mg)

stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate package: 28 days.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel./Fax: + 48 (81) 886 33 53, Tel.: + 48 (81) 888 91 00
e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel: + 48 (81) 888 91 33, + 48 509 750 444
e-mail: biowet@biowet.pl

Package size: 250 ml
Shelf life: 3 years

For animal use only.
Prescription veterinary medicine.
To be administered exclusively by a veterinarian.

Marketing authorisation number: 789/99
SPC: 2024-09-26

don’t waste time on diarrhea

Rehydrat

Electrolyte preparation for calves, lambs, kids, piglets, and foals
(glucose, sodium chloride, sodium bicarbonate, potassium chloride)

- replenishes electrolytes and provides energy
- supports acid-base balance
- helps counteract the negative effects of diarrhea
- comes in a new doypack with a zip-lock for easy resealing and multiple use

Composition:
glucose, sodium chloride, sodium bicarbonate, potassium chloride
Nutritional additive/kg: zinc sulfate heptahydrate 2.5 g
Analytical constituents/kg: chloride 96.2 g, sodium 70 g, potassium 26.7 g
crude protein <0.5%, crude fiber 0.6%, crude fat <1.0%, crude ash 23.7%

Rehydrat®
– Replenishes electrolytes
– Supports acid-base balance
– Counteracts the adverse effects of diarrhea
– Provides energy

Properties and indications
Rehydrat restores and maintains the proper balance of water and electrolytes. Glucose facilitates water absorption, serves as a readily available source of energy, and enhances the palatability of the product. Bicarbonate ions act as a blood buffer system, helping to prevent metabolic acidosis. Zinc plays a role in intestinal mucosal repair, alleviating symptoms associated with diarrhea.

Rehydrat is recommended for use in cases of dehydration and electrolyte loss caused by:
– Gastrointestinal disorders accompanied by diarrhea
– Increased physical exertion
– High ambient temperatures

Dosage and administration
Preparation of solution:
Dissolve one sachet (280 g) in 10 liters of water.
Administer 0.5 – 1.0 liter per 10 kg of body weight per day, divided into 2 – 5 portions.
Recommended duration of product use: 1 to 7 days (1 to 3 days if used as the sole source of nutrition).
Animals must have access to fresh water at all times.
Rehydrat is best used after consultation with a veterinarian.

Storage conditions
Store at room temperature in the original packaging.
Protect from light and moisture.
Net weight: 280 g
Shelf life: 18 months

For animal use only
Dietetic feed mixture for calves, lambs, kids, piglets and foals supporting water-electrolyte balance

Veterinary identification number: αPL0614003p
Leaflet preparation date: 2025-02-28

professional protection against dehydration

Rehydrat C

Electrolyte supplement for calves, lambs, kids and foals
(glucose, psyllium husk, sodium bicarbonate, sodium chloride, potassium chloride, magnesium oxide)

- ensures proper hydration
- improves intestinal peristalsis
- stimulates regeneration and growth of intestinal cells
- regulates gut flora
- replenishes electrolytes

Composition per 100 g
Glucose (carbohydrate source) – 40.0 g
Psyllium seeds *(Plantago ovata)* – 27.0 g
Dried brewer's yeast – 8.0 g
Wheat starch – 7.3 g
Sodium bicarbonate – 7.0 g
Sodium chloride – 5.0 g
Potassium chloride – 3.5 g
Magnesium oxide – 1.0 g

Additives per 100 g
Amino acids:
3c451 L-glutamine – 0.2 g (2,000 mg/kg)
Vitamins:
3a315 Vitamin PP (nicotinamide) – 0.8 g (8,000 mg/kg)
3a700ii Vitamin E (alpha-tocopherol acetate) – 0.2 g (2,000 mg/kg)
Analytical Composition
Sodium – 4.0%, potassium – 1.8%, chlorides – 8.5%, magnesium – 0.53%, crude protein – 4.76%, crude fiber – 0.3%, crude fat – <1%, crude ash – 15.1%.

Indications and properties
Used in cases of water-electrolyte imbalance to support physiological digestive functions. Recommended for dehydration and digestive disturbances accompanied by diarrhea. The fiber in psyllium seed husks absorbs water, forming a gel that protects the intestinal mucosa. Glutamine promotes the regeneration of intestinal cells.

Administration
It is recommended to consult a veterinarian before use.
Preparation of solution:
Calves and foals:
Mix 100 g (1 sachet) with 2 liters of water or milk at a temperature of 40°C.
Lambs and kids:
Mix 25 g (1/4 sachet) with 0.5 liters of water or milk at a temperature of 40°C.
Prepare and administer within a maximum of 20 minutes before the solution turns into a gel.
The solution is recommended to be administered every 12 hours:
– For 1 to 7 days
– For 1 to 3 days if it is the only source of nutrition
Animals must have access to fresh water at all times.

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

Packaging
Carton containing 10 sachets x 100 g
Shelf life: 2 years

Dietetic feed mixture intended for calves, lambs, kids, and foals

Veterinary Identification Number: αPL0614003p
Leaflet preparation date: 2025-03-27

Sedazin

Injection solution intended for cattle, horses, dogs and cats
(xylazine 20 mg/ml)

Active substance and excipient content

Xylazine (in the form of hydrochloride) 20 mg/ml

Therapeutic indications

Sedazin is used in cattle, horses, dogs and cats for sedation, reduction of pain, myorelaxation and as a premedication agent. Administration of xylazine facilitates examination of irritable animals, application of drugs and facilitates conduction of short surgical procedures.

Contraindications

Do not use in the case of ventricular arrhythmia, hypotension and in a shock.

Do not use in the case of respiratory diseases.

Do not use in advanced pregnancy (risk of miscarriage), except for the labour.

Do not use in the case of diabetes (xylazine reduces the level of insulin).

Do not use in the case of alimentary obstruction in dogs and cats.

Adverse reactions

Respiratory weakness with concomitant acidosis, bradycardia, hypotension, frequent urination. Ataxia in large animals, profuse perspiration in horses. Ruminants may experience ruminal atony and flatulence, salivation and diarrhoea.

In cats, less frequently in dogs, vomiting occurs within 3-5 minutes after administration. Sometimes diarrhoea occurs in dogs and cats.

Local reactions may occur after intramuscular or subcutaneous administration, but they normally subside after 48 hours.

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

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

Routes of administration: intramuscular, intravenous and subcutaneous administration.

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

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

In order to determine appropriate dosage, the animal's body weight should be measured as accurately as possible.

In the case of a cardiac disorder, the product should be administered in combination with atropine.

The effect of xylazine begins within 5-10 minutes after intramuscular administration and 3-5 minutes after intravenous administration. Its analgesic effect remains for 10-15 minutes and the sedative effect for 0.5-4 hours, depending on the animal species. The effect after intramuscular administration lasts longer.

Instructions for use

None

Withdrawal period

Cattle and horses:

edible tissues – zero days,

milk – zero days.

Dogs and cats – not applicable.

Special warnings and precautions

Special precautions for use in animals:

Horses:

- Xylazine hinders physiological intestinal peristalsis. Therefore, it should only be used in horses in colics resistant to analgesics. Do not use in horses with impaired motility of the caecum,
- Use carefully in horses susceptible to laminitis,
- In horses with respiratory disorders or respiratory diseases, life-threatening breathlessness might develop,
- The lowest recommended doses should be used.

Cats and dogs:

- Xylazine inhibits regular intestinal motility, which is conducive to gas accumulation in the gastrointestinal tract of the animals. Therefore, the use of xylazine is not recommended before an x-ray examination of the stomach and the foregut because the accumulated gas hampers proper interpretation of the examination results,
- In brachycephalic dog breeds with symptoms of impaired respiratory function or respiratory diseases, 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.

Sedazin

Injection solution intended for cattle, horses, dogs and cats
(xylazine 20 mg/ml)

Avoid administering too high doses of the drug. Adjust dosage considering individual sensitivity of each animal.
Exercise particular caution when using the drug in convulsions, acute renal or hepatic insufficiency and in dehydrated animals.
In order to prevent choking on saliva or vomit, the animal's head should be positioned lower than the rest of the body.
Old and fatigued animals may be more sensitive to the effect of xylazine whereas agitated animals may require higher doses.
During the use of the product, peace should be provided for patients because external stimuli may deteriorate reaction to the product.
Xylazine may impair thermoregulation. If ambient temperature differs from room temperature, cooling or warming the patient is recommended during the use of the product.
In the case of painful procedures, xylazine should be used in combination with local or general anaesthesia.
Treated animals should be monitored until the effects of the product subside completely. During this time, they should be kept in a separate room in order to avoid injuries from other animals.
Drugs with a central neurodepressive effect (anaesthetics, analgesics) boost the effect of xylazine. Intensification of the cardiodepressive effect, weakening of respiratory action and hypotensive effect occurs. Therefore, the combination of xylazine and opioids is used with great caution.
Xylazine should not be combined with thiobarbiturates and halothane due to the consequent intensification of cardiac arrhythmia.
Due to the risk of ventricular arrhythmia, xylazine should not be combined with adrenaline and other drugs stimulating the sympathetic nervous system or used immediately after their administration.
Do not use xylazine in advanced pregnancy because it may lead to miscarriage.
In overdose, adverse effects are intensified: there is a risk of respiratory arrest and collapse; convulsive seizures may occur.
Partial elimination of the effect of xylazine may be obtained by administration of central antagonists of α2-adrenergic receptors: yohimbine in the dose of 0.1 – 0.2 mg/kg b.w. intravenously or tolazoline in the dose of 0.5 – 1.0 mg/kg b.w. intravenously.
Since no studies of the conformity of this veterinary medicinal product have been conducted, this product must not be combined with other medicinal veterinary products.

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

If the product is accidentally swallowed or self-injected, immediately seek medical advice and show the package leaflet to the physician, but do not drive due to the possibility of sedation and changes in the arterial blood pressure.
Avoid contact with skin, eyes and mucosa.
In the case of contact of the product with bare skin, wash the skin with plenty of water immediately.
Remove contaminated clothing being in direct contact with the skin.
If the product has accidental contact with an eye, wash the eye with plenty of water. In the case of any symptoms, you should contact a physician.
If a pregnant woman administers the medicinal product, she should take special precautions to prevent self-injection due to the possibility of the occurrence of uterine contractions and reduced foetal arterial blood pressure after accidental general exposure.

Indications for physicians

Xylazine is an agonist of alpha-2-adrenergic receptors. Its absorption may induce dose-dependent clinical symptoms such as: sedation, respiratory depression, bradycardia, hypotension, dryness in the oral cavity and hypoglycaemia. Ventricular arrhythmia was also reported. Respiratory and hemodynamic disorders should be treated symptomatically.

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Package sizes: 20 ml and 50 ml
Shelf life: 2 years

For animal treatment only.
Prescription veterinary medicine.
Tobe administered under veterinary supervision.

Name and address of the manufacturer responsible for batch release:
Biowet Puławy Sp. z o.o.
ul. H. Arciucha 2, 24-100 Puławy
Tel/fax: 81 886 33 53; e-mail: sekretariat@biowet.pl

Marketing authorization number: 219/96
SPC: 2013-01-09

Streptovac

Inactivated vaccine against streptococcosis in pigs
Injectable emulsion

Composition

Inactivated *Streptococcus suis* antigens:
serotype 2, concentration before inactivation min. 8.5 x 108 CFU/dose,
serotype 1/2, concentration before inactivation min. 8.5 x 108 CFU/dose.

Excipients:

Aluminium hydroxide gel
Water oil emulsion

Target species

Pigs

Indications for use

Passive immunisation of piglets via active immunisation of pregnant sows, and active immunisation of piglets, to reduce mortality, clinical signs and (or) pathogenic lesions caused by Streptococcus suis.
Onset of immunity: 2 weeks after vaccination.
Duration of immunity: has not been established.
Strength of immunity is to a large extent determined by proper nutrition and hygienic conditions.

Contraindications

Do not use in diseased animals.

Special warnings

Special precautions for safe use in the target species:
None
Special precautions to be taken by the person administering the veterinary medicinal product to animals:
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy and lactation.
Interaction with other medicinal products and other forms of interaction:
No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.
Overdose:
No adverse events have been observed after administration of a double dose.
Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Adverse events

Target species: pigs

Frequency unknown, cannot be determined based on available data:	Fever[1] Inflammatory reaction[2]

[1] Core body temperature rises by 2°C within a few hours after product administration. Body temperature gets back to normal without administration of treatment.
[2] Occurs at the injection site, subsides spontaneously.

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

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

The product should be administered as two 2 ml doses at the time interval of 2-3 weeks.
Piglets should be vaccinated immediately before weaning and 2-3 weeks later, using a dose of 2 ml injected intramuscularly in the neck area.
Pregnant sows should be immunised between 5 and 2 weeks before parturition.

Advice on correct administration

Before the start of vaccination, transfer the product to room temperature and thoroughly mix the bottle contents immediately before injection.
Use sterile needles and syringes. During vaccination, it is recommendable to mix the package content from time to time.
Vaccination should be planned so as to use the entire package contents during one day.

Withdrawal period(s)

Zero days.

Special storage precautions

Keep out of the sight and reach of children.
Store in a refrigerator (2°C – 8°C). Protect from light. Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging is 1 day.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

Streptovac

Inactivated vaccine against streptococcosis in pigs
Injectable emulsion

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Contct details

Marketing authorisation holder and manufacturer responsible for batch release:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel./Fax: + 48 (81) 886 33 53, Tel.: + 48 (81) 888 91 00
e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel: + 48 (81) 888 91 33, + 48 509 750 444
e-mail: biowet@biowet.pl

Package size: 100 ml
Shelf life: 1 year

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

Marketing authorization: 1709/06
SPC: 2025-02-10

Suiferrin

Injection solution intended for cattle and pigs (iron (III) as a dextran complex 100 mg/ml)

Statement of the active substance(s) and other ingredient(s)

Each ml contains:

Active substance:

Iron (III) hydroxide dextran complex 100 mg

Excipients:

Phenol 5 mg

Dark brown solution.

Target species

Cattle (calves), pigs (piglets, weaners).

Indications for use

Prevention and treatment of iron-deficiency anaemia. This veterinary medicinal product corrects iron deficiency in the body, it stimulates the haematopoietic system to produce haemoglobin, it raises red blood cell levels.

Contraindications

Do not use in case of hepatic impairment and renal failure.

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

Do not use in case of anaemia other than iron-deficiency anaemia.

Special warnings

Special precautions for safe use in the target species:

Iron dextran in weaners can induce anaphylaxis. The causes may include genetic factors, and vitamin E and/or selenium deficiency.

In case of suspected vitamin E and/or selenium deficiency, do not administer products containing iron compounds.

Do not give the product by routes of administration other than recommended. Intravenous use may lead to acute poisoning manifested primarily in anaphylaxis. Possible effects may include sudden death without prodromal symptoms or symptoms of the nervous system, such as balance disorders, progressive depression leading to a coma. After per os administration, animals can experience vomiting blood, diarrhoea or constipation.

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

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

Interaction with other medicinal products and other forms of interaction:

The product should not be administered with oral products containing iron.

It is not recommended to use the product with tetracyclines and chelating agents as iron ions may form sparingly soluble complexes preventing absorption.

Overdose:

Overdosing the product may cause gastrointestinal tract disorders: vomiting blood, diarrhoea or constipation. Elevated iron levels can cause shock, cardiac disorders leading to collapse, dyspnoea and renal failure manifested by oliguria or anuria.

Signs of chronic iron overload result from liver disorders caused by accumulation of iron in hepatocytes and Kupffer cells.

Major incompatibilities:

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

Adverse events

Target species: cattle, pig.

Rare (1 to 10 animals/10 000 animals treated):	Anaphylaxis[1]
Frequency unknown (cannot be determined based on the available data):	Death[2] Reaction at the injection site[3] Hypersensitive reaction[4]

[1] Occurs in weaners. The causes may include genetic factors, vitamin E or selenium deficiency.

[2] The causes may include genetic factors, vitamin E or selenium deficiency.

[3] Irritation, oedema and brown pigmentation of adjacent tissues may occur at the injection site.

[4] May occur in piglets in case of significant vitamin E and/or selenium deficiency in sow's diet. Hypersensitivity is manifested by nausea, vomiting and sudden death within about one hour after administration of products containing iron.

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

Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49 21 687, Fax: +48 22 49 21 605

E-mail: pw@urpl.gov.pl, Website: https://smz.ezdrowie.gov.pl

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

Intramuscular or subcutaneous use.

Piglets, weaners: 2 ml/animal

Calves: 4-8 ml/animal.

Advice on correct administration

None.

Withdrawal period(s)

Meat and offal: zero days

Special precautions for storage

Keep out of the sight and reach of children.

Do not store above 25°C.

Store in the original package to protect from light.

Do not freeze.

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

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

Suiferrin

Injection solution intended for cattle and pigs
(iron (III) as a dextran complex 100 mg/ml)

Special precautions for disposal
Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Contact details
Marketing authorisation holder and manufacturer responsible for batch release:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel./Fax: + 48 (81) 886 33 53, Tel: + 48 (81) 888 91 00
e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel.: + 48 (81) 888 91 33, Tel: +48 509 750 444
e-mail: biowet@biowet.pl

Package sizes: 100 ml and 250 ml
Shelf life: 3 years

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

Marketing authorization number: 2087/11
SPC: 2025-06-17

Sultrim

Injection solution intended for cattle, horses and pigs (sulfadoxine 200 mg/ml, trimethoprim 40 mg/ml)

Composition

Active substances:

Sulfadoxine 200 mg/ml

Trimethoprim 40 mg/ml

Clear, yellow brown solution.

Target species

Cattle, horses, pigs.

Indications for use

Cattle:

Bacterial pneumonia in calves caused by *Pasteurella multocida, Mannheimia haemolitica, Corynebacterium pyogenes, Staphylococcus spp., Streptococcus spp.*

Bacterial gastroenteritis in calves caused by *Salmonella spp., Proteus spp.*

Colibacillosis in calves caused by *Escherichia coli.*

Metritis in cows caused by *Staphylococcus spp., Streptococcus spp., Escherichia coli, Haemophilus somnus, Corynebacterium pyogenes, Pseudomonas spp.*

Listeriosis caused by *Listeria monocytogenes*.

Pododermatitis caused by *Fusobacterium necrophorum, Bacteroides melaninogenicus and Actinomyces pyogenes.*

Horses:

Respiratory infections caused by S*taphylococcus spp., Streptococcus spp., Actinobacillus equi, Rhodococcus equi, Pasteurella spp.*

Gastrointestinal infections caused by *Rhodococcus equi, Actinobacillus equi, Salmonella spp.*

Pigs:

Bacterial respiratory tract infections caused by *Streptococcus suis, Actinobacillus pleuropneumoniae, Actinobacillus suis, Bordatella bronchiseptica, Haemophilus parasuis, Pasteurella multocida.*

Bacterial joint inflammation caused by *Arcanobacterium pyogenes, Escherichia coli, Staphylococcus spp., Streptococcus spp.*

Colibacillosis in piglets caused by *Escherichia coli.*

Bacterial gastroenteritis in piglets caused by *Salmonella choleraesuis.*

Metritis in sows, MMA syndrome caused by S*taphylococcus spp., Streptococcus spp., Escherichia coli, Klebsiella spp.*

Atrophic rhinitis caused by *Bordatella bronchiseptica, Mannheimia haemolytica and Pasteurella multocida.*

Contraindications

Do not use in cases of hypersensitivity to the active substance-(s) or to any of the excipients.

Do not use in animals with hepatic and/or renal failure.

Do not use in pregnant animals.

Do not use in animals with blood dyscrasia.

Do not use in dehydrated animals.

Special warnings

Special warnings:

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

Special precautions for safe use in the target species:

Large doses of the product should be administered intravenously.

In case of intravenous administration, inject the product slowly.

The maximum dose injected intramuscularly or subcutaneously should not exceed 20 ml per one site.

The product should be used based on susceptibility test results and local regulations governing the use of sulphonamides.

Underdosing or too short duration of treatment may promote the development of drug resistance.

Sulphonamides combined with trimethoprim, especially after prolonged treatment, might cause folate deficiency and deficiency in vitamins produced by gut microbiota.

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

The product should be administered slowly to avoid accidental self-injection. Wash hands after usage

In case of contact with eyes or skin, immediately flush the affected site with plenty of water.

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

People with known hypersensitivity to sulfadoxine or trimethoprim should avoid contact with the veterinary medicinal product, or administer the product with caution. The product should not be administered by pregnant women.

Special precautions for the protection of the environment:

Not applicable.

Pregnancy and lactation:

Do not use during pregnancy.

The product can be used during the lactation period.

Interaction with other medicinal products and other forms of interaction:

The product should not be administered simultaneously with detomidine.

Sulphonamides may compete for blood protein-binding sites with other drugs, such as methotrexate, phenylbutazone, thiazide diuretics, salicylates, probenecid, and phenytoin. Urinary acidifying agents, such as ascorbic acid and ammonium chloride, are likely to increase the risk of precipitation of sulphonamides in the urinary system.

Trimethoprim might increase the efficacy of antithrombotic agents, such as warfarin, by inhibiting its metabolism.

Overdose:

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

Major incompatibilities:

None known.

Dosage for each target species, routes and method of administration

Horses, cattle, pigs: 13.33 mg of the product/kg body weight, which corresponds to 1 ml of the product/15 kg body weight injected intravenously, intramuscularly or subcutaneously, once daily for 4 to 6 days.

Advice on correct administration

In case of intravenous injection, administer the product very slowly, at the same controlling the animal's respiration and heart rate, as well as the colour of the conjunctiva.

Sultrim

Injection solution intended for cattle, horses and pigs
(sulfadoxine 200 mg/ml, trimethoprim 40 mg/ml)

Adverse events

Frequency unknown, cannot be determined based on available data:	Swelling at the injection site[1] Hypersensitivity reactions[2] Impaired renal function[3]

[1] Painful, spontaneously resolving oedema at the injection site may appear after intramuscular or subcutaneous injection.
[2] Elicited especially after rapid intravenous injection.
[3] Caused by precipitation of sulphonamide in renal tubules, especially in dehydrated animals, animals with aciduria, or after administration of high doses.

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

Withdrawal periods

Meat and offal:
Cattle, horses, pigs:
– intravenous administration – 6 days
– intramuscular administration of up to 4 ml of the product – 15 days
– intramuscular or subcutaneous administration of more than 4 ml of the product – 30 days

Milk:
Cattle: 4 days

Special storage precautions

Keep out of the sight and reach of children.
Store below 25°C. Protect from light. Do not freeze. Store in the original, closed package
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate package: 28 days

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Pack size: 100 ml

Prescription veterinary medicine.
To be administered under veterinary supervision.

Marketing authorisation number: 2729/17
SPC: 2023-09-22

simple ketosis diagnosis in cows

Testoket

Rapid test for detecting ketone bodies
in cow urine or milk
(sodium nitroprusside, ammonium sulfate, anhydrous sodium carbonate)

- detects ketone bodies in urine or milk
- easy-to-perform test
- quick test results

Composition
Sodium nitroprusside, ammonium sulfate, sodium carbonate anhydrous.

Characteristics
Sodium nitroprusside from the test kit reacts with ketone bodies contained in milk or urine, giving colours from pink to violet (depending on ketone body content).

Directions for use
Testoket is a ready-to-use disposable test to be used outside laboratory. Pour 3-4 ml of tested liquid (urine or milk) into a test tube with the reagent, seal with a stopper and shake.
Check colour change within up to 2 minutes.
Urine testing:
– in healthy cows, reagent and urine do not change colour,
– in cows with subclinical ketosis, reagent and urine turn pink,
– in cows with clinical ketosis, reagent and urine turn violet.
Milk testing:
– in healthy cows and cows with subclinical ketosis, reagent and milk do not change colour,
– appearance of pink to violet colour confirms clinical ketosis.

Warnings
Do not freeze!
Keep out of the reach and sight of children.

User precautions
Toxic effect after consumption and inhaling. Avoid skin and eye contamination. Do the test wearing protective gloves. In case of skin or eye contact, immediately flush the affected site with profuse amount of water.
In case of accidental consumption, provide large amounts of water to drink, induce vomiting.
Immediately seek doctor's advice and present the doctor with packaging.
Neutralize the unused test material or any residues thereof, in accordance with binding safety regulations.

Storage
Store at below 25°C. Protect from light.

Pack content: 10 x 1g
Shelf life: 18 months.

For veterinary use.
For self-administration by the animal owner.
For animal use only.

Marketing authorizarion number: PL/WR 000045
Leaflet preparation date: 2013-10-25

Tiamfenikol Biowet Puławy

Injection solution intended for cattle
(thiamphenicol 250 mg/ml)

Composition

Active substance:

Thiamphenicol – 250 mg

Excipients:

Qualitative composition of excipients and other constituents

Propylene glycol

Dimethylacetamide

Clear solution opalescent in brown.

Indications for use

Recommended in the treatment of:

– respiratory diseases caused by *Bordetella bronchiseptica, Haemophilus spp., Klebsiella spp., Pasteurella spp.,*

– gastrointestinal diseases caused by *Escherichia coli, Salmonella spp.,*

– metritis caused by *Staphylococcus spp., Streptococcus spp., Listeria monocytogenes, Brucella spp., Haemophilus spp., Escherichia coli,*

– wounds infected by bacteria of the genus S*taphylococcus spp., Streptococcus spp., Proteus spp.*

Contraindications

Do not use in case of hypersensitivity to thiamphenicol.

Do not administer simultaneously with beta-lactam antibiotics.

Secial warnings

Special warnings:

The product may be less effective when administered in inflammatory conditions of the reproductive and urinary systems, and peritonitis with severe hepatic and renal dysfunction.

Special caution should be taken when administering the product to animals with end-stage renal failure or with inflammatory and degenerative lesions of the liver.

Special precautions for safe use in the target species:

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

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

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

Pregnancy:

Do not use in pregnant animals.

Lactation:

When using the product during the laying period, observe the 48-hour withdrawal period for milk.

Interaction with other medicinal products and other forms of interaction:

The product acts synergistically with oxytetracycline and macrolides.

Do not administer the product simultaneously with beta-lactam antibiotics.

Overdose:

Laboratory studies in rats have shown evidence of toxicity, with a lethal dose of 10 g/kg body weight in case of per os administration. For ruminants, lethal dose has not been established. No toxic effect has been found in cattle after administration of doses higher than recommended doses (of up to 60 mg/kg body weight).

Major incompatibilities:

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

Adverse events

Target species: cattle

Rare (1 to 10 animals/10 000 animals treated):	Skin rash, lowered red blood cell (erythrocyte) count and haemoglobin. These symptoms may occur during long-term use of high therapeutic doses of the product.
Frequency unknown, cannot be determined based on available data:	Minor pain at the injection site, subsiding spontaneously.

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

Dosage for each target species, routes and method of administration

The product is intended for intramuscular injection in the following doses:

25-50 mg of thiamphenicol/kg body weight/24 hours.

Administer the product in two separate doses, every 12 hours in the amount of 1-2 ml/20 kg body weight.

Treatment should be administered for 3 to 7 days.

Advice on correct administration

None.

Withdrawal period(s)

Meat and offal: 8 days.

Milk: 48 hours.

Special storage precautions

Keep out of the sight and reach of children.

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

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

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

Tiamfenikol Biowet Puławy

Injection solution intended for cattle
(thiamphenicol 250 mg/ml)

Special precautions for disposal
Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Contact details
Marketing authorisation holder and manufacturer responsible for batch release:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel./Fax: + 48 (81) 886 33 53, Tel.: + 48 (81) 888 91 00
e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel: + 48 (81) 888 91 33, + 48 509 750 444
e-mail: biowet@biowet.pl

Package size: 100 ml

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

Marketing authorization: 1550/04
SPC: 2023-09-29

Vitaminum B_1 Biowet Puławy

Injection solution intended for cattle, sheep, horses, chickens, turkeys and dogs (thiamine hydrochloride – 25 mg/ml)

Composition:

1 ml contains:

Active substance:

Thiamine hydrochloride – 25 mg

Excipient:

Phenol 2,25 mg

Target species

Cattle, sheep, horse, chicken, turkey and dog

Indications for use

Vitamin B_1 deficiency and avitaminosis:

– in carnivorous animals on raw fish diet

– in animals artificially nourished using glucose infusions,

– conditions of increased metabolism (fevers, pregnancy, lactation).

Treatment of the following conditions in target species:

– cattle, sheep, horses: reduced viability of newborns.

– dogs: inflammation and paralysis of peripheral nerves, rheumatoid arthritis, nervous form of canine distemper, muscle weakness and digestive disorders leading to vitamin B deficiency.

– chickens, turkeys: ataxia, spasms, paralysis, muscle atrophy, polyneuritis.

Contraindications

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

Special warnings

Special precautions for safe use in the target species:

Do not administer the product intravenously as this might cause an anaphylactic shock.

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

After accidental contact with eyes, irritation resulting in dacryorrhea might occur. In this case, flush the eye immediately with plenty of lukewarm water or saline solution. Particular caution should be taken to avoid self-injection during administration of the product.

In the case of self-injection, especially intravenous self-injection, an anaphylactic shock, breathing disturbances and temporary hypotension might occur. After self-injection, seek medical help immediately and show the information leaflet or packaging to the doctor.

Special precautions for the protection of the environment:

Not applicable.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Laying birds:

The product can be used during the laying period.

Interaction with other medicinal products and other forms of interaction:

Administration of amprolium (particularly in turkeys) may cause thiamine deficiency.

Do not use the product together with iron solutions. Avoid administering the drug in combination with plants with high thiaminase content as its excess causes decomposition of vitamin B_1.

Overdose:

Acute poisonings in animals occur only when the recommended dose is exceeded many times. Overdose symptoms include convulsions, cyanosis, breathing difficulties and lower blood pressure. Symptoms of chronic poisoning do not occur as vitamin B_1 is a water-soluble vitamin and it is not accumulated in the body as its excess is excreted in urine.

Thiamine overdose effects have not been observed in clinical practice. No medical intervention is necessary even if the recommended doses are exceeded.

Major incompatibilities:

Sulphates contained in the drinking water may cause decomposition of vitamin B_1. Do not administer the product with neutral or alkaline solutions, as they may cause decomposition of thiamine.

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

Adverse events

Acute pain resulting from the irritating effect of thiamine might occur during administration of the drug (especially in dogs).

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

Dosage for each species, routes and method of administration

Use subcutaneously or intramuscularly once daily in the following doses until clinical symptoms subside:

cattle, sheep, horses: 0.5 ml of the product/10 kg b.w., which corresponds to 12.5 mg of vitamin B_1/10 kg b.w.

chickens, turkeys, dogs: 0.1 ml of the product/1 kg b.w., which corresponds to 2.5 mg of vitamin B_1/1 kg b.w.

Advice on correct administration

Do not administer the product intravenously as this might cause an anaphylactic shock.

In order to administer the product properly, follow the instructions contained in this leaflet.

Withdrawal periods

Meat and offal:

cattle, sheep, horses, chickens, turkeys – zero days

Eggs:

turkeys – zero days

Milk:

cattle – zero days

sheep – zero days

dogs – not applicable.

Vitaminum B_1 Biowet Puławy

Injection solution intended for cattle, sheep, horses, chickens, turkeys and dogs (thiamine hydrochloride – 25 mg/ml)

Special storage precautions
Keep out of the sight and reach of children.
Store below 25°C. Protect from light. Do not freeze.
Store in a closed container.
Do not use this veterinary medicinal product after its expiry date given on the label. The expiry date refers to the last day of that month.

Special precautions for disposal
Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Contact details
Marketing authorisation holder and manufacturer responsible for batch release:
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e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse reactions:
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e-mail: biowet@biowet.pl

Pack size: 50 ml

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

Marketing authorization number: 969/00
SPC: 2023-11-17

Vitaminum C Biowet Puławy

Injection solution intended for horses, cattle, pigs, sheep, dogs, cats and foxes

(ascorbic acid 100 mg/ml)

Statement of the active substance(s) and other ingredient(s)

Each ml contains:

Active substance:

Ascorbic acid 100 mg

Clear, yellow solution.

Target species

Horse, cattle, pig, sheep, dog, cat, fox.

Indications for use

Treatment of vitamin C deficiency, support in antibiotic therapy, treatment of digestive disorders, during pregnancy and exposure to stress, weakening and exhaustion. Support in the treatment of urinary tract infections.

Contraindications

Calcium oxalate stone.

Special warnings

Special precautions for safe use in the target species:

Intramuscular injection may lead to topical irritation (especially in horses).

Significant pain may occur during injection of the product.

More acidic urine may induce precipitation of urates, oxalates and citrates, leading to the formation of stone in the urinary tract.

In animals diagnosed with diabetes and suffering from excessive absorption of iron from the gastrointestinal tract, avoid administration of ascorbates in doses higher than recommended.

Parenteral administration of ascorbic acid in doses higher than recommended leads to false positive laboratory results pointing to the presence of glucose in the blood.

Keep special caution when using vitamin C with deferoxamine in old animals. If there is a need to administer the two medicines at the same time, it is recommended to administer the ascorbic acid two hours after the infusion of deferoxamine.

In case of intravenous administration, warm the product to body temperature and inject slowly.

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

Accidental self-injection of this veterinary medicinal product poses no threat to the person administering the product.

Pregnancy and lactation:

The product can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

Ascorbic acid adds to the effect of coumarin anticoagulants. It increases iron absorption. Flavonoid glycosides enhance the effect of vitamin C.

By making urine more acidic, ascorbic acid reduces the antibacterial effect of aminoglycosides and macrolides. Simultaneous administration of vitamin C and iron-binding deferoxamine used for treating secondary hemochromatosis and transfusion hemosiderosis, may lead to iron overload, primarily in cardiac cells, which produces rhythm and conductions disorders. When administered intravenously, ascorbic acid reduces the half-life of salicylamide.

Simultaneous administration of oxytocin and ascorbic acid impairs the ascorbic acid's capability to cross the placenta to get to the foetus.

Overdose:

Administration of ascorbic acid in doses exceeding the recommended doses may lead to urine acidification, which leads to impaired excretion of weak acids and bases. Excessive intake of vitamin C may cause diarrhoea and reduced absorption of anticoagulants from the gastrointestinal tract.

Administration of multiple doses of ascorbic acid exceeding 4 g may lead to inactivation of vitamin B12, transient reduction of neutrophil's phagocytosis and bactericidal function, excessive absorption of iron ions and formation of kidney stone.

Major incompatibilities:

Ascorbic acid is incompatible with sodium bicarbonate, sodium salicylate, sodium nitrate, theobromine, hexamethylenetetramine (methenamine), chlorpromazine hydrochloride, methylprednisolone sodium succinate.

Do not mix the ascorbic acid solution with other veterinary medicinal products for injection.

Adverse events

Horses, cattle, pigs, sheep, dogs, cats and foxes:

Frequency unknown (cannot be determined based on the available data):	Kidney stone [1]

[1] may occur in animals predisposed to develop kidney stone.

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

Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49 21 687, Fax: +48 22 49 21 605

E-mail: pw@urpl.gov.pl, Website: https://smz.ezdrowie.gov.pl

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

Intravenous or intramuscular use.

This veterinary medicinal product is to be administered 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.

This veterinary medicinal product should be administered for 5 to 7 days (it is recommended to administer half a dose twice daily)

Advice on correct administration

In case of intravenous administration, warm the product to body temperature and inject slowly.

Vitaminum C Biowet Puławy

Injection solution intended for horses, cattle, pigs, sheep, dogs, cats and foxes
(ascorbic acid 100 mg/ml)

Withdrawal period(s)
Meat and offal:
Horse, cattle, pig, sheep – zero days
Milk:
Cattle, sheep – zero 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 expiry date which is stated on the label after "Exp". The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate packaging: 28 days.

Special precautions for disposal
Medicines should not be disposed of via wastewater or household waste.
Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Contact details
Markting authorisation holder and manufacturer responsible for batch release:
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e-mail:biowet@biowet.pl

Package size: 100 ml
Shelf life: 2 years

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

Marketing authorisation number: 991/00
SPC: 2025-05-23

Biowet Puławy 105 YEARS OF PRODUCTING VETERINARY MEDICINES

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