

# Offer for dogs and cats



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

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

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

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### Active ingredients and products list

#### **Ascorbic acid**

Vitaminum C Biowet Puławy – injectable solution

#### Betaglucan

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

#### Biotin

• Olderm – compound preparation, capsules twist-off.

#### Calcium (chloride/gluconate/phosphate)

- Calcii borogluconas 25% inj. injectable solution
- Calmagluc compound preparation, injectable solution

#### Caffeine

• Coffenal – injectable solution

#### Chondroitin (sulfate), glucosamine (hydrochloride)

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

#### Colostrum

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

#### Cranberry

- Veturino compound preparation, capsules
- Veturino forte compound preparation, capsules

#### **Enrofloxacin**

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

#### **Flumethasone**

• Vecort - injectable solution

#### Gentamicin

• Gentamycyna Biowet Puławy – injectable solution

#### Glucosamine

- Veturino compound preparation, capsules
- Veturino forte compound preparation, capsules

#### Glucos

- Calmagluc compound preparation, injectable solution
- Injectio Glucosi 40% injectable solution

#### **Hyaluronic acid**

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

#### Iodine, sodium iodide

Hyalsept – compound preparation, gel

#### Iron (complexed with dextran)

Suiferrin – injectable solution

#### Ketamine

• Ketamina Biowet Puławy – injectable solution

#### L-arginine

- Biohepanex Advance Small compound preparation, capsules
- Biohepanex Advance Large compound preparation, capsules
- NeoplasmaVet amino compound preparation, capsules

#### L-glutamine

- Biohepanex Advance Small compound preparation, capsules
- Biohepanex Advance Large compound preparation, capsules
- NeoplasmaVet amino compound preparation, capsules

#### L-methionine

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

#### L-theanine

- Veturino compound preparation, capsules
- Veturino forte compound preparation, capsules

#### Magnesium (chloride/gluconate)

• Calmagluc – injectable solution

#### **Medroxy progesterone (acetate)**

• Depogeston – injectable suspension

#### xytocın

Oxytocinum Biowet Puławy – injectable solution

#### **Ornithine**

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

#### Pentobarbital, sodium pentobarbital

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

#### Permethrin

• Insectin – powder

#### Phospholipids

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

#### Quercetir

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

#### Sodium metamizole

• Injectio Pyralgini Biowet Puławy – injectable solution **Soy lecithin** 

- Biohepanex Advance Small compound preparation, capsules
- Biohepanex Advance Large compound preparation, capsules

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

Polisulfamid – compound preparation, injectable solution

#### Taurine, trans-resveratrol

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

#### Thiamine (hydrochloride)

• Vitaminum B<sub>1</sub> Biowet Puławy – injectable solution

#### Vitamins A, E, B<sub>1</sub>, B<sub>6</sub>, B<sub>12</sub>

Olderm – compound preparation, capsules twist-off.

#### Vitaminum C

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

#### VitaminumD₃

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

#### Xylazine

• Sedazin - injectable solution

#### Zinc

Olderm – compound preparation, capsules twist-off.

#### Other preparations (care products)

- Deodent compound preparation, oral solution
- Oticlar compound preparation, liquid



### Index of products by therapeutic indication

### Anesthetics, sedatives, and euthanasia

agents

Ketamina Biowet Puławy

Morbital

Morbital Plus

Sedazin®

#### Antibiotics and sulfonamides

Enflocyna® 50 mg/ml, inj.

Enflocyna® Sol

Gentamycin Biowet Puławy

Polisulfamid®

#### Calcium and electrolyte products

Calcii borogluconas 25% inj.

Calmagluc®

#### **Cardiovascular and stimulant products**

Coffenal

#### Corticosteroids (systemic)

Vecort

#### **Dermatological products**

Hyalsept

Olderm

#### **Ectoparasite control products**

Insectin®

#### **Gastrointestinal products**

Biohepanex Advance Small

Biohepanex Advance Large

#### **Hormonal products**

Depogeston®

Oxytocinum Biowet Puławy

#### **Immune-stimulating products**

Bioimmunex canis

Bioimmunex felis

Canifos betaglukan

#### Mineral and vitamin products

Canifos®

Canifos® betaglukan

Canifos® junior

Vitaminum B1 Biowet Puławy

Vitaminum C Biowet Puławy

#### Pain and antipyretic products

Injectio Pyralgini Biowet Puławy

Vecort

#### **Products for musculoskeletal disorders**

Bioarthrex

Bioarthrex HA

#### Skin and ear care products

Deodent®

Mastiprewent®

Oticlar®

#### **Urinary system products**

Urometin

Urometin forte

Veturino

Veturino forte



### Index of animal species and products

#### Dogs

- Biohepanex Advance Small compound preparation, capsules
- Biohepanex Advance Large compound preparation, capsules
- Bioimmunex canis compound preparation, capsules
- Calcii borogluconas 25% inj. injection solution
- Calmagluc compound preparation, injection solution
- Canifos compound preparation, tablets
- Canifos betaglucan compound preparation, tablets
- Canifos junior compound preparation, tablets
- · Coffenal injection solution
- Deodent compound preparation, oral liquid
- Depogeston injection suspension
- Enflocyna 50 mg/ml injection solution
- Enflocyna Sol oral solution
- Gentamycin Biowet Puławy injection solution
- Hyalsept compound preparation, gel
- Injectio Glucosi 40% injection solution
- Injectio Pyralgini Biowet Puławy injection solution
- · Insectin powder
- Ketamina Biowet Puławy injection solution
- Morbital compound preparation, injection
  solution
- Morbital Plus compound preparation, injection solution
- NeoplasmaVet compound preparation, capsules
- Olderm compound preparation, capsules twist-off.
- · Oticlar compound preparation, liquid
- Oxytocinum Biowet Puławy injection solution
- Polisulfamid compound preparation, injection solution
- Sedazin injection solution
- Urometin compound preparation, capsules
- Urometin forte compound preparation, capsules
- Vecort injection solution
- · Veturino compound preparation, capsules
- Veturino forte compound preparation, capsules
- Vitaminum B<sub>1</sub> Biowet Puławy injection solution
- Vitaminum C Biowet Puławy injection solution

#### Cats

- Biohepanex Advance Small compound preparation, capsules
- Bioimmunex felis compound preparation, capsules
- Coffenal injection solution
- Deodent compound preparation, oral liquid
- Depogeston injection suspension
- Enflocyna 50 mg/ml injection solution
- Gentamycyna Biowet Puławy injection solution
- Hyalsept compound preparation, gel
- Iniectio Glucosi 40% iniection solution
- Ketamina Biowet Puławy injection solution
- Morbital compound preparation, injection solution
- Morbital Plus compound preparation, injection solution
- NeoplasmaVet amino compound preparation, capsules
- Olderm compound preparation, capsules twist-off.
- Oticlar compound preparation, liquid
- Oxytocinum Biowet Puławy injection solution
- Sedazin injection solution
- Urometin compound preparation, capsules
- · Vecort injection solution
- Veturino compound preparation, capsules
- Vitaminum C Biowet Puławy injection solution





# Bioarthrex

Tablets for dogs supporting cartilage regeneration and the function of the musculoskeletal system (glucosamine, chondroitin, devil's claw extract, L-carnitine, vit. C)





strengthens and regenerates joint cartilage

ensures proper joint function and the dog's mobility

Dicalcium phosphate – 766 mg Glucosamine (from animal tissues) – 500 mg Chondroitin sulfate – 400 mg Potato starch – 250 mg Processed animal protein (poultry) – 150 mg

Wheat starch – 118 mg

Wileat Starch - Fromg

Brewer's yeast (Saccharomyces cerevisiae) - 70 mg

Magnesium stearate (fatty acid salt) – 50 mg

Porcine gelatin –  $20\,mg$ 

Sensory Additive:

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

**Dietary Additives:** 

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

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

3b503/Manganese sulfate monohydrate – 400 mg/kg

**Analytical Constituents:** 

Crude ash - 27.49%

Crude protein – 14.28%

Crude fat – 1.02%

Crude fiber - < 1.0%

#### **Properties**

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

#### Recommended for:

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

#### Dosage and administration

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

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

Tablets can be mixed with food for easier administration.

#### Storage conditions

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

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

#### Complementary feed for dogs.

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



# joint cartilage regeneration



# Bioarthrex HA

Tablets for dogs with sodium hyaluronate supporting joint function (glucosamine, chondroitin, devil's claw extract, L-ca

(glucosamine, chondroitin, devil's claw extract, L-carnitine, vitamin C, sodium hyaluronate)





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

#### Composition (per 2.5 g tablet):

Dicalcium phosphate – 600 mg

Glucosamine (from animal tissues) - 500 mg

Chondroitin sulfate - 400 mg

Potato starch – 250 mg

Processed animal protein (poultry) - 150 mg

Wheat starch - 118 mg

Brewer's yeast (Saccharomyces cerevisiae) - 70 mg

Magnesium stearate (fatty acid salt) – 50 mg

Porcine gelatin - 20 mg

Sodium hyaluronate – 15 mg

Sensory Additive:

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

**Dietary additives:** 

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

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

3b503/Manganese sulfate monohydrate – 400 mg/kg

Analytical constituents:

Crude ash - 20.44%

Crude protein - 13.95%

Crude fat – 1.0%

Crude fiber - < 1.0%

#### **Properties**

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

#### Recommended for:

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

#### Dosage and administration

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

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

Tablets can be mixed with food for easier administration.

#### Storage conditions

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

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

#### Complementary feed for dogs.

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





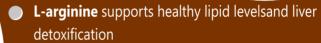
liver protection and regeneration



### Biohepanex Advance Small

Capsules for small breed dogs and cats, supporting liver function





- L-glutamine promotes digestive system regeneration and provides energy to the liver
- phospholipids rebuild liver cells, protect against steatosis, and support fat digestion

#### **Composition:**

Wheat starch,

Fatty acid salt (magnesium stearate)

Nutritional additives/amino acids per kg:

3c363 L-arginine 99.256 mg

3c451 L-glutamine 99,256 mg

Technological additive/emulsifier per kg:

1c322 Soy lecithin 99,256 mg (source of phosphatidylcholine)

Technological additive/anti-caking agent:

1e551b Colloidal silica

Technological additive/stabilizer:

1c460i Microcrystalline cellulose

Capsule shell:

Porcine and bovine gelatin

Sensory additive E172 Red iron oxide

Analytical constituents:

crude protein 46%, crude fat 4.8%, crude fiber 14.9%, crude ash 2.7%, moisture 6.8%

The ingredients in Biohepanex Advance Small support liver regeneration and proper liver function. They aid liver metabolism and participate in digestion of fats. L-arginine helps maintain normal blood lipid levels and supports liver detoxification. L-glutamine positively influences the regeneration of the digestive system and provides energy to liver cells. Lecithin aids in the reconstruction of liver cells, helping to prevent fatty liver.

#### Indications:

- liver damage, to improve its function
- digestive disorders
- supportive in biliary tract diseases
- preventive for liver protection
- -supportive in cats showing symptoms of hepatic encephalopathy

#### **Dosage and administration:**

Cats: 1 capsule daily

Dogs: 1 capsule per 5 kg of body weight once daily

If necessary, the capsule can be opened and its contents mixed with food.

It is recommended to use the product for 1 to 3 months, and up to 6 months in cases of chronic liver insufficiency.

It is recommended to consult a veterinarian before use.

#### Storage conditions:

Store in the original packaging, at room temperature, in a dry place. Protect from light and moisture.

Package size: 40 openable capsules (403 mg/capsule)

Complementary feed for small breed dogs and cats.

Veterinary Identification Number: 06148301 Leaflet preparation date: 2025-08-11







### Biohepanex Advance Large

Capsules for medium and large breed dogs, supporting liver function



- regenerates the liver and facilitates digestion
- supports biliary tract diseases
- phospholipids protect liver cells, supporting their regeneration
- L-arginine supports liver detoxification
- L-glutamine provides energy to liver cells

#### **Composition:**

Wheat starch

Fatty acid salt (magnesium stearate)

Nutritional additives/amino acids per kg:

3c363 L-arginine 110 345 mg

3c451 L-glutamine 110 345 mg

Technological additive/emulsifier per kg:

1c322 Soy lecithin 206 897 mg (source of phosphatidylcholine)

Technological additive/anti-caking agent:

1e551b Colloidal silica

Technological additive/stabilizer:

1c460i Microcrystalline cellulose

Capsule shell:

Porcine and bovine gelatin

Sensory additive E172 Red iron oxide

Analytical constituents:

crude protein 49.2%, crude fat 8.7%, crude fiber 13.1%, crude ash 3.1%, moisture 5.9%

#### **Properties:**

The ingredients in Biohepanex Advance Large support liver regeneration and proper liver function. They aid liver metabolism and participate in digestion of fats. **L-arginine** helps maintain normal blood lipid levels and supports liver detoxification. **L-glutamine** positively influences the regeneration of the digestive system and provides energy to liver cells. **Lecithin** aids in the reconstruction of liver cells, helping to prevent fatty liver.

#### **Indications:**

- liver damage to improve its function
- digestive disorders
- supportive in biliary tract diseases
- preventive for liver protection

#### Dosage and administration:

1 capsule per 15 kg of body weight once daily.

If necessary, the capsule can be opened and its contents mixed with food.

It is recommended to use the product for 1 to 3 months, and in the case of chronic liver insufficiency, up to 6 months.

It is recommended to consult a veterinarian before use.

#### Storage conditions:

Store in the original packaging, at room temperature, in a dry place. Protect from light and moisture.

Package size: 40 openable capsules (725 mg/capsule)

Complementary feed for medium and large breed dogs.

Veterinary Identification Number: 06148301 Leaflet preparation date: 2025-08-11







# Bioimmunex canis

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





- protects against infections
- neutralizes free radicals

#### Composition per capsule:

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

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

E460 / Microcrystalline Cellulose 361,011 mg

E551b / Colloidal Silica 7,220 mg

Capsule shell: porcine gelatin

Sensory additives per kg:

E172 / yellow iron oxide 3,026 mg

E132 / indigo carmine 1,316 mg

Analytical constituents:

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

#### **Properties:**

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

#### **Indications:**

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

#### Dosage and administration:

1 capsule per 20 kg of body weight once daily.

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

Bioimmunex Canis should ideally be used after consulting a veterinarian.

#### Storage conditions:

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

Protect from light and moisture.

**Shelf life:** 2 years

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

#### Complementary feed for dogs.

Veterinary identification number: 06148301 Leaflet preparation date: 2024-11-04







# Bioimmunex felis

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





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

#### **Composition per Capsule**

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

Technological additives/Anti-caking agents per kg:

E460 / microcrystalline cellulose – 283,286 mg

E551b/colloidal silica - 5,666 mg

<u>Capsule shell:</u> Porcine-bovine gelatin

Sensory additives per kg:

E172 / Yellow iron oxide – 3,000 mg

E132 / Indigotine – 1,300 mg

Analytical constituents:

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

#### **Properties**

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

#### Indications

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

#### Administration

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

Bioimmunex Felis is best used after consultation with a veterinarian

#### **Storage conditions**

Store in the original packaging at room temperature in a dry

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

#### Shelf life: 2 years

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

#### Complementary feed for cats.

Veterinary identification number: 06148301 Leaflet preparation date: 2024-11-04



# Calcii borogluconas 25% inj.

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

#### Composition

1 ml contains:

#### **Active substance:**

Calcium gluconate 216.6 mg

#### **Excipient:**

Chlorocresol 0.9 mg **Therapeutic indications** 

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

(Downer cow syndrome). As a supportive drug in the treatment of hypomagnesemic tetany, inflammatory and allergic conditions, particularly

acute ones and with redness, as well as in cases of swelling and reduced blood oagulation.

#### **Contraindications**

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

#### **Adverse reactions**

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

In order to identify the symptoms of over-dosage at a proper time, the heart beat should be monitored during the infusion.

In intramuscular and subcutaneous injections, and also in peri-intravenous administration some local reactions in a form of transient swelling can occur.

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

### Posology per each species, routes and methods of administration

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

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

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

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

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

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

#### Recommendations for proper administration

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

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

#### Withdrawal period

Horse, cattle, pigs:

Edible tissues - zero days,

Milk-zero days,

Dog - not applicable.

#### Special precautions for storage

Keep out of the sight and reach of children.

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

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

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

#### **Special warnings**

Special precautions for use in animals:

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

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.

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

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

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

Thiazide diuretics should not be administered.

#### Pharmaceutical incompatibilities:

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

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

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

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

Shelf life: 2 years

Available containers: 250 ml.

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

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









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 gluconate60 mgCalcium hypophosphite22 mgMagnesium chloride hexahydrate30 mgGlucose monohydrate100 mg

#### **Excipient:**

Phenol 2.6 mg

Clear, colourless or slightly yellow solution.

#### Indications for use

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

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

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

#### **Contraindications**

Hyperparathyroidism and renal failure.

Hypercalcaemia, acidosis.

Hypermagnesemia, Myastenia gravis in dogs, heart conduction disorders.

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

#### **Special warnings**

#### Special warnings:

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

Special precautions for safe use in the target species:

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

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

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

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

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

Take special caution to avoid self-injection.

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

Wash hands after use.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:

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

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

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

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

#### Overdose:

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

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

#### Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal









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

product must not be mixed with other veterinary medicinal products.

#### **Adverse events**

Target species: horses, cattle, pigs, dogs.

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

Hypercalcemia<sup>1</sup>

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

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

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

https://smz.ezdrowie.gov.pl

### Dosage for each target species, routes and method of administration

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

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

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

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

Acute disorders with advanced hypocalcaemia and hypom-

agnesaemia, such as parturient paresis and tetany caused by hypomagnesaemia – administer a dose of 1.0-1.5 ml/kg 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











Tablets for dogs supporting growth and development





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

#### Composition per 2.5 g:

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

brewer's yeast (Saccharomyces cerevisiae) - 70 mg

pork gelatin - 40 mg

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

calcium - 620 mg

phosphorus - 408 mg

magnesium – 19 mg

potassium – 1.4 mg

sodium - 0.9 mg

zinc - 0.275 mg

iron - 0.036 mg

manganese - 0.023 mg

Analytical Constituents:

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

#### **Properties and indications**

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

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

Canifos is recommended to balance the diet with essential nutrients.

#### **Dosage and administration**

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

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

The tablet can be mixed with food.

#### Storage conditions

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

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

#### Complementary mineral feed for dogs.

Veterinary identification number: 06148301 Leaflet preparation date: 2023-11-22



### fetch for health





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



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

#### Composition per 2.5 g:

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

#### **Analytical Constituents:**

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

#### Trace Elements per 2.5 g:

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

#### **Properties and indications**

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

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

#### Dosage

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

#### Storage conditions

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

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

#### Complementary mineral feed for dogs.

Veterinary identification number: 06148301 Leaflet preparation date: 2024-10-24



### healthy, strong bones



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





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

#### Composition per 2.5 g:

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

#### Analytical constituents:

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

#### Trace Elements per 2.5 g:

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

#### **Properties and indications**

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

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

#### Dosage:

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

#### **Storage Conditions**

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

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

#### Complementary mineral feed for dogs.

Veterinary identification number: 06148301 Leaflet preparation date: 2024-10-24







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 carni-

vores, 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 <sup>1</sup> Anxiety <sup>24</sup> , hyperactivity <sup>24</sup> , vocalizing <sup>24</sup> Convulsions <sup>3</sup> Increased heart rate <sup>24</sup> , arrhythmia <sup>2</sup> Increased respiratory rate <sup>24</sup> Gastrointestinal tract disorders <sup>5</sup> Increased creatine phosphokinase activity <sup>4,6</sup>
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<sup>&</sup>lt;sup>1</sup> may occur after subcutaneous injection and is related to the irritating drug effect

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

 $Subcutaneous, in tramuscular \ or \ in travenous \ use.$ 

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





<sup>&</sup>lt;sup>2</sup> may occur after intravenous injection of the product

<sup>&</sup>lt;sup>3</sup> may occur after intravenous injection of the product in animals diagnosed with epilepsy

<sup>&</sup>lt;sup>4</sup> may occur in piglets with porcine stress syndrome

 $<sup>^{\</sup>mathtt{5}}$  may occur as a result of increased gastric glands secretion

<sup>&</sup>lt;sup>6</sup> may occur within 45 minutes after caffeine administration





# 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





### to breathe freely





Liquid to prevent bad breath in dogs and cats z jamy ustnej psów i kotów



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

#### Composition

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

#### Characteristics

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

Fluoride prevents dental caries and strengthens tooth enamel.

Citric acid dissolves mineral plaque.

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

#### **Indications**

Eliminating unpleasant odour from the mouth.

Teeth cleaning and care.

#### **Directions for use**

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

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

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

Use the product after each meal.

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

#### Storage

Keep at a temperature not exceeding +25°C.

Protect from light.

Do not freeze.

#### Warnings

Keep out of the reach and sight of children.

Shelf life: 18 months

#### Available container

Spray bottles containing 50 ml of the product.

Leaflet preparation date: 2013-10-25



# Depogeston



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

#### Statement of the active substance(s) and other ingredient(s) **Active substance:**

Medroxyprogesterone acetate - 50 mg/ml

#### **Excipients:**

Methyl parahydroxybenzoate – 1.2 mg/ml Propyl parahydroxybenzoate – 0.2 mg/ml

White suspension with sediment at the bottom, homogeneous after shaking.

#### **Target species**

Dog, cat.

#### Indications for use

Prevention of oestrus in bitches and queens.

Treatment of nymphomania in queens, not related to ovarian

#### **Contraindications**

Do not use:

- in the proestrus, oestrus, metoestrus phase,
- during pregnancy and lactation,
- in case of diagnosed mammary gland cancer,
- in juvenile and growing animals,
- do not use before the first heat.
- in animals with diabetes.
- in inflammations of the reproductive system,
- in whippet/greyhound bitches,
- in case of known sensitivity to the active substance or any of the excipients.

#### **Special warnings**

#### Special warnings:

Before product administration, it is recommended to conduct relevant laboratory tests to determine the phase in the oestrus cycle.

#### Special precautions for safe use in the target species:

The first dose of the product should be administered not earlier than 2 weeks after parturition and not later than 1 month prior to the expected heat.

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

Pregnant women and women of childbearing potential should avoid contact with the product. In case of accidental spillage onto skin or eye contact, flush the contaminated site with water. 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.

Do not use during lactation. Administration of the product during lactation reduces production of milk by the mammary gland due to inhibited gonadotropin secretion by the pituitary gland.

Interaction with other medicinal products and other forms of interaction:

Administration of gonadotropins (LH, FSH) and estrogens to restore the oestrus cycle following product use may increase the risk of pathological lesions in the endometrium.

#### Overdose:

Overdosing the product may cause transient changes in animal temperament, increased appetite, induce lactation. Adverse events likely to occur after long-term use of the product have been described in item 6.

#### 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: dog, cat.

ты д р			
Rare (1 to 10 animals/10 000 animals treated):	Hyperpigmentation or skin and hair discolouration 1		
Frequency unknown (cannot be determined based on the available data):	Pyometra <sup>2,3</sup> , proliferative endometrium <sup>3</sup> , cystic endometrial hyperplasia <sup>3</sup> , ovarian cysts <sup>3</sup> , acromegaly <sup>3</sup> , mammary gland cancer <sup>3</sup> . Inhibited adrenal function, diabetes, Changes in animal temperament <sup>4</sup> , increased appetite		

- <sup>1</sup> May occur at the injection site.
- <sup>2</sup> May occur in bitches.
- <sup>3</sup> Administration of medroxyprogesterone for more than 2 years is conducive to the development of diseases of the uterus and mammary gland.
- <sup>4</sup> Is of transient nature.

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

#### Advice on correct administration

Shake before use to obtain a homogeneous suspension.

#### Withdrawal period(s)

Not applicable

#### Special precautions for storage

Keep out of the sight and reach of

Store below 25°C. Do not freeze.

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

immediate packaging: 28 days.





# Depogeston



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

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

Subcutaneous or intramuscular use in the following doses: <u>bitches:</u> 50 – 100 mg of medroxyprogesterone acetate per animal subcutaneously or intravenously: i.e.

- small animals (less than 10 kg b.w.) 1.0 ml of the product per animal;
- medium-sized (10-25 kg b.w.) 1.5 ml of the product per animal;
- large (25-45 kg b.w.) 2.0 ml of the product per animal; queens: 50 mg of medroxyprogesterone acetate per animal subcutaneously, i.e. 1.0 ml of the product per animal.

The first dose of the product should be administered not earlier than 2 weeks after parturition and not later than 1 month prior to the expected heat.

In order to permanently block the cycle, administer the product regularly in bitches every 5 months in bitches and every 3 to 4 months in queens, however for no longer than 2 years. Animal owners should be made aware that the onset of the first heat following the use of the product depends on animal's specific characteristics and it usually occurs after 5 to 6 months in bitches and 3 to 4 months in queens, although this may be longer in some instances.

#### 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

Pack size: 6 ml Shelf life: 3 years

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

Marketing authorization number: SPC: 2025-06-18









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

#### Composition

Each ml contains:

#### **Active substance:**

Enrofloxacin – 50 mg

#### **Excipient:**

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

#### **Target species**

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

#### Indications for use

#### Cattle (calves)

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

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

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

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

#### Sheep

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

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

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

#### Goats

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

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

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

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

#### Pias

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

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

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

#### Doas

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

#### Cats

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

#### **Contraindications**

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

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

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

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

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

#### Special warnings

Special precautions for safe use in the target species:

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

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

Do not use the product to treat less acute infections.

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

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

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

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

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

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











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

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

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

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

Pregnant women should avoid contacting the veterinary medicinal product directly.

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

Wash hands after use.

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

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

#### Pregnancy and lactation:

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

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

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

Interaction with other medicinal products and other forms of interaction:

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

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

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

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

#### Overdose:

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

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

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

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

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

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

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

#### Adverse events

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

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

<sup>&</sup>lt;sup>1</sup>These signs are usually mild and transient.

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

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

for Registration of Medicinal Products, Medical Devices and Biocidal Products

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<sup>&</sup>lt;sup>2</sup> May be observed in calves. The signs may persist for up to 14 days.

<sup>&</sup>lt;sup>3</sup> May be observed in pigs. Inflammation may persist for up to 28 days after injection.

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





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

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

Intravenous, subcutaneous or intramuscular administration.

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

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

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

#### Sheep and goats:

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

Inject subcutaneously.

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

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

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

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

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

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

Inject subcutaneously.

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

#### Advice on correct administration

In case of multiple injections, rotate injection sites.

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

#### Withdrawal period(s)

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

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

#### Sheep:

Meat and offal - 4 days.

Milk-3 days.

Goats:

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

Meat and offal - 13 days.

#### Special storage precautions

Keep out of the sight and reach of children.

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

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

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

#### Special precautions for disposal

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

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

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

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

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

Package size: 100 ml Shelf life: 2 years

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

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





# Enflocyna Sol



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

#### Composition

Each ml contains:

#### **Active substance:**

Enrofloxacin – 50 mg

#### **Excipient:**

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

#### **Target species**

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

#### Indications for use

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

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

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

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

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

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

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

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

#### **Contraindications**

Do not use as a preventive measure.

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

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

Do not use in calves with developed forestomach.

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

#### **Special warnings**

Special warnings:

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

Special precautions for safe use in the target species:

Principles of prudent use:

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

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

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

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

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

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

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

Pregnancy and lactation:

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

The product can be used in the laying period.

Interaction with other medicinal products and other forms of interaction:

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

#### Overdose:

Enrofloxacin displays low toxicity after single-dose administration, and low acute toxicity. LD<sub>so</sub> 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<sup>1</sup>

Gastrointestinal disorders <sup>1</sup> Nervous system disorders <sup>1</sup>

<sup>1</sup> 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

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https://smz.ezdrowie.gov.pl

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

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

for 3 to 5 days.

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

for 3 to 5 days.

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

for 3 to 5 days.

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

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

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

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

Salmonellosis: 0.4 ml/kg body weight, corr. to 4 ml/1 litre of water daily for 3 days or 2 ml/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:  $0.1 \, \text{ml/kg}$  body weight, corr. to ml/litre of water for  $3 \, \text{to} \, 4 \, \text{days}$ .

#### Advice on correct administration

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

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

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

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

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

#### Withdrawal period(s)

Meat and offal:

Calves, pigs: 10 days,

Hens: 7 days,

Turkeys: 13 days,

Dogs – not applicable.

Do not use in pigeons intended for human consumption.

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

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

#### **Special storage precautions**

Keep out of the sight and reach of children.

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

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

#### 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





# Gentamycyna Biowet Puławy



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

#### Composition

#### **Active substance:**

Gentamicin (gentamicin sulfate) – 50 mg/ml

#### **Excipients:**

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

#### **Target species**

Dogs, cats.

#### Indications

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

#### **Contraindications**

Do not use in pregnant animals.

Do not use in animals with renal failure.

Do not use in animals allergic to aminoglycosides.

Do not use in severely dehydrated animals.

#### **Special warnings**

Special warnings:

None.

Special precautions for safe use in the target species:

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

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

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

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

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

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

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

#### Pregnancy and lactation:

Do not use during pregnancy.

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

Interaction with other medicinal products and other forms of interaction:

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

#### Overdose:

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

#### Major incompatibilities:

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

Do not administer in combination with anaesthetics or muscle relaxers.

#### Adverse events

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

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

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





# Gentamycyna Biowet Puławy



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

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

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

https://smz.ezdrowie.gov.pl

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

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

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

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

Urine alkalinization increases antibiotic activity.

#### Advice on correct administration

None

#### Withdrawal period(s)

Not applicable.

#### **Special storage precautions**

Keep out of the sight and reach of children.

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

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

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

#### Special precautions for disposal

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

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

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

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

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

Package size: 50 ml Shelf life: 3 years

For animal use only.

Prescription veterinary medicine.

Administration under veterinary supervision.

Marketing authorization number: 281/96 SPC: 2023-12-14





### ישיאת דורו היים ורות ב

### 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 or 20 ml of Hyalsept, equipped with a cannula for multiple extractions of the gel, packed in a cardboard box

Shelf life: 24 months

Leaflet preparation date: 2024-03-22



# Injectio Glucosi 40% 🔊



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

#### Active substance and excipient content

Glucosum monohydricum 400 mg/ml

#### Therapeutic indications

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

#### **Contraindications**

- Hyperglycaemia
- Water intoxication
- Hypotonic dehydration and acidosis.

#### **Adverse reactions**

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

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

### Posology per each species, routes and methods of administration

Administer the product slowly intramuscularly in the following doses:

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

#### Recommendations for proper administration

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

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

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

#### Withdrawal period

Dogs, cats – not applicable Cattle, horses, sheep, swine, goats Edible tissues – zero days Milk – zero days.

#### Special precautions for storage

Keep out of the sight and reach of children.

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

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

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

#### **Special warnings**

Special precautions for use in animals

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

In diabetic patients, administer glucose only in the case of lifethreatening hypoglycaemia induced by insulin overdose.

Use with caution in animals with adrenal insufficiency and in anuria.

During a long-lasting use, fluid balance, concentration of electrolytes and acid-base balance should be monitored.

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

Caution should be taken to avoid self-injection.

Glucose might cause serious physiological changes which are dangerous to a pregnant female and foetus. Therefore, the product should not be used in pregnancy except in absolute necessity and with particular caution.

No contraindications for use in lactation.

Glucose overdose causes hyperglycaemia and osmotic diuresis, which in consequence leads to cellular dehydration.

In the case of overdose, apply symptomatic treatment.

In physiological conditions, glucose present at excessive concentrations in the circulatory system after reaching the renal threshold is excreted through the kidneys. A healthy body is capable of maintaining glucose homeostasis and, as a result of polydipsia and polyuria, maintain the correct glucose level

Glucose should not be combined in solutions with barbiturates, sulphonamides, erythromycin, hydrocortisone and vitamin  $B_{12}$ .

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

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

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

Available containers: 250 ml

Shelf life: 2 years

For animal treatment only.
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

<u>Dogs:</u> not applicable.

#### Special precautions for storage

Store in the original container in order to protect from light. Store at a temperature below 25°C.

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

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

#### **Special warnings**

Special precautions for use in animals:

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

Special precautions for people administering veterinary medicinal product to animals:

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

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

#### Pregnancy:

The product can be used in pregnancy.

#### Lactation:

The product can be used during lactation.

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









# Powder for cutaneous use for dogs and pigeons (permethrin – as cis/trans 25:75 – 10 mg/g)

#### Active substance

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

#### Therapeutic indications

Insectin is intended for the control of ectoparasite infestations: fleas and ticks in dogs, as well as lice and soft ticks in pigeons.

#### **Contraindications**

Do not use in puppies under 12 weeks of age.

Do not use in lactating females.

Do not use in pigeons under 1 month of age.

Do not use in cats. This product may cause severe adverse reactions in cats, including fatal outcomes; therefore, any contact with the product must be avoided. If dogs and cats are kept together, they must be separated for 72 hours following treatment. Ensure that cats do not lick the fur of a treated dog. If this occurs, seek veterinary assistance immediately.

Do not use in cases of hypersensitivity to the active substance or any excipient.

#### **Adverse reactions**

In dogs, adverse reactions are rare and may include excessive salivation, vomiting, diarrhea, mild muscle tremors, and hyperactivity progressing to depression.

Birds have low sensitivity to permethrin. Adverse reactions affecting the nervous system are exceptionally rare.

If any adverse reactions occur after using this product, or if any unusual symptoms not listed in this leaflet are observed (including reactions in humans due to contact with the product), report them to the appropriate veterinarian, the responsible entity, or the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products. The reporting form can be downloaded from

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

#### Dosage for each species and method of administration

Small dogs: 5–10 g Medium dogs: 10–15 g Large dogs: 15–20 g Pigeons: 1–2 g

Ten applications (shakes of an inverted container) deliver approximately 2.5–3.0 grams of the product onto the skin.

#### Instructions for proper use

This product is for external use only.

Sprinkle the product over the entire body of the animal, parting the fur or feathers to reach the skin. Avoid dusting around the eyes, ears, nose, and mouth. Leave the product on for several hours, then brush the fur.

]After each treatment, replace the animal's bedding. Repeat the treatment every 2–3 weeks.

#### Withdrawal period

Dogs - not applicable.

Do not use in pigeons intended for human consumption.

#### Special precautions for storage

Keep out of sight and reach of children.

Store in a dry place at a temperature below 25°C.

Keep away from human food and animal feed.

Do not use this veterinary medicinal product after the expiry date indicated on the label. The expiry date refers to the last day of the specified month.

#### Special warnings

For each target species:

For external use only.

Do not rub the product into the animal's skin.

To maximize flea eradication, use an appropriate insecticidal treatment in the animal's environment (disinfect bedding, kennels, etc.). It is also recommended to treat all animals kept together.

Precautions for use in animals:

Prevent licking of the product.

Protect the animal's eyes during application.

Precautions for individuals administering the veterinary medicinal product:

The treatment should be carried out outside of living quarters. Avoid excessive dust formation and inhalation of the product. Use general precautions when handling ectoparasiticides, including wearing gloves and protective masks. Avoid contact with eyes. Wash hands after application. If accidental contact occurs with skin or mucous membranes, rinse the affected area immediately with clean water.

Keep children away from treated animals.

Do not allow treated animals to interact with humans, especially children, until the product is removed from their coat

Individuals with known hypersensitivity to permethrin should avoid contact with the product.

Other precautions:

Treated dogs should not be allowed to swim in bodies of water for at least three weeks after application.

Pregnancy and Lactation

 $Do \ not \ use \ during \ pregnancy \ or \ lactation.$ 

**Laying Period** 

Do not use in laying birds.

Interactions with Other Medicinal Products and Other Forms of Interaction

None known.

Overdose (Symptoms, Emergency Procedures, Antidotes, if necessary)

In case of overdose, intensive symptomatic treatment should be implemented, as there is no specific antidote.

It is recommended to administer sedative, anticonvulsant (diazepam, pentobarbital, propofol), and muscle relaxant medications.

Fluid therapy with crystalloid solutions (physiological saline or multi-electrolyte solutions) is advised.

Affected animals should be bathed in lukewarm water with mild detergents to remove any residual permethrin from the skin.

#### Pharmaceutical Incompatibilities

As compatibility studies have not been conducted, this veterinary medicinal product must not be mixed with other veterinary medicinal products.







## Powder for cutaneous use for dogs and pigeons (permethrin – as cis/trans 25:75 – 10 mg/g)

#### Special Precautions for Disposal of Unused Veterinary Medicinal Products or Waste Derived from Such Products

This veterinary medicinal product is highly toxic to bees, fish, and crustaceans.

Do not dispose of medicinal products via wastewater or household waste.

Consult a veterinarian for proper disposal methods to help protect the environment.

#### **Additional Information**

For further information on this veterinary medicinal product, please contact the responsible entity.

Package Size: 50 g Shelf Life: 2 years

For animal use only.

Available without a veterinary prescription – OTC.

To be administered by the animal's owner or caregiver.

Marketing authorization number: 742/99 SPC: 2015-02-02













# Ketamina Biowet Puławy



### Injection solution intended for dogs and cats (ketamine 100 mg/ml)

#### Composition

Each ml contains

#### **Active substance:**

Ketamine – 100 mg

(ketamine hydrochloride – 115.34 mg)

#### **Excipient:**

Chlorobutanol hemihydrate – 3 mg

Clear, colourless liquid.

#### Indications for use

Short-lasting general anaesthesia for minor surgeries requiring analgesia, such as: removal of tartar, removal of foreign bodies from the oral cavity and the oesophagus, incision of abscesses, dressing change, x-ray examinations, clinical examinations of aggressive and excitable animals.

Long-lasting general anaesthesia in combination with other anaesthetics to induce general anaesthesia, for example in operations of fractures, reduction of dislocation, castration, amputation, caesarean section, laparotomy.

#### **Contraindications**

Do not use in animals with circulatory failure, hypertension, liver or kidney damage.

Do not use in animals with epilepsy, ocular hypertension, open globe injuries and head injuries.

Do not use in case of hypersensitivity to ketamine or chlorobutanol

#### **Special warnings**

#### Special warnings:

Do not give any food to animals within 12 hours before administration of the product.

Abdominal surgeries require administration of appropriate analgesics, as ketamine does not relieve visceral sensations.

As ketamine does not eliminate laryngeal reflex, increases salivation and tracheobronchial secretion in procedures on the nasopharynx, larynx, trachea and bronchi, as well as in endoscopy, the product should be used in combination with agents relieving the aforementioned effects of ketamine.

#### Special precautions for safe use in the target species:

Ketamine may increase salivation and airway secretions, which may lead to choking and airway obstruction.

During anaesthesia, remember to protect eyes against drying of the cornea.

During recovery of animals anaesthetised using ketamine, the following symptoms might occur: hallucinations, delirium, ataxia, hypersensitivity to touch, hyperreactivity, aggression. During recovery, animals should be provided with peace and quiet and protection against self-mutilation.

In case of excessive loss of blood, the ketamine dose should be reduced.

As ketamine increases the heart rate and myocardial oxygen demand, it must be used with caution in patients with cardiomyopathy.

Ketamine causes moderate respiratory depression, frequently reduces the respiratory rate and respiratory volume. After ketamine administration, a characteristic type of respiration occurs involving long periods of apnoea after intake of breath. Therefore, during anaesthesia, cardiovascular and pulmonary function should be monitored.

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

This veterinary medicinal product is a highly potent drug. Special caution should be taken to avoid self-injection. In case of accidental self-injection, the person administering the product may experience analgesia, and after approximately 10 minutes loss of consciousness persisting for 10 to 15 minutes. Upon recovery, the person may experience amnesia and hallucinations. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Do not drive. In case of contact with skin or mucous membranes, flush the affected area with water immediately.

#### Pregnancy:

Do not use in pregnant animals, except during the caesarean section procedure.

#### Lactation:

Do not use during the lactation period.

Interaction with other medicinal products and other forms of interaction:

Xylazine, detomidine, medetomidine, acepromazine prevent seizures that may accompany ketamine-induced anaesthesia. Ketamine action is enhanced by other agents that weaken the function of the central nervous system.

Narcotic agents, barbiturates, diazepam may prolong recovery.

Chloramphenicol may prolong the anaesthetic action of ketamine

Neuromuscular blockers, e.g. succinylcholine and tubocurarine, may enhance or prolong respiratory depression.

Thiopental prevents ketamine-induced brain metabolism and dilation of cerebral vessels.

Atropine prevents excessive salivation after ketamine administration.

#### Overdose:

Exceeding the recommended doses induces respiratory depression. A dose eight times the recommended dose causes respiratory paralysis, whereas a dose twelve times the recommended dose leads to circulatory arrest.

Administration of excessively high doses of the drug might induce vomiting and muscle tremor.

In case of an overdose, mechanical resuscitation methods should be considered – maintain respiration and do cardiac massage.

Special restrictions for use and special conditions for use:

The product is intended to be administered only by a veterinarian.

#### Major incompatibilities:

Do not use ketamine simultaneously with barbiturates due to their chemical incompatibility.





# Ketamina Biowet Puławy



### Injection solution intended for dogs and cats (ketamine 100 mg/ml)

#### Adverse events

Very rare (< 1 animal/10 000 animals treated, including isolated reports):	Respiratory depression <sup>1</sup> , pulmonary oedema Hypertension, tachycardia, cardiac arrest Seizures
Frequency unknown (cannot be determined on the basis of available data):	Increased muscle tension, spasticity, tonic muscle contractions Increased salivation, vomiting Mydriasis, nystagmus, loss of the palpebral reflex <sup>2</sup> Vocalisation <sup>3</sup>

<sup>&</sup>lt;sup>1</sup> moderate

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

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

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

Intramuscular or intravenous administration

Before administration of ketamine, use premedication by injecting atropine in a dose of 0.05 mg/kg body weight intramuscularly or subcutaneously.

#### Dogs:

- 2–5 mg of ketamine/kg body weight intravenously
- 5–15 mg of ketamine/kg body weight intramuscularly Cats:
- 5–15 mg of ketamine/kg body weight intramuscularly Administration of ketamine simultaneously with other anaesthetics and premedication agents before general anaesthesia:

**Cats** administer atropine in a dose of 0.05 mg/kg body weight by intramuscular injection, followed by xylazine or diazepam, and after a few minutes ketamine in a dose of 5–15 mg /kg bodyweight

**Dogs** administer atropine in a dose of 0.05 mg/kg body weight by intramuscular injection, followed by an antipsychotic (diazepam, medetomidine or xylazine), and after 5 to 10 minutes ketamine in a dose of 3 mg /kg body weight intravenously, or 10 mg/kg body weight intramuscularly.

Onset of general anaesthesia will start after 3 to 5 minutes following intramuscular injection. Ketamine action usually lasts for 20 to 45 minutes. The higher the dose, the longer the duration of anaesthesia.

Dose size does not impact anaesthetic depth.

Majority of animals are able to get up after approximately 2 hours.

#### Advice on correct administration

In case of intravenous administration, warm the veterinary medicinal product to body temperature and inject slowly.

#### Withdrawal period(s)

Not applicable

#### **Special storage precautions**

Keep out of the sight and reach of children.

Store below 25 °C.

Protect from light.

Do not freeze.

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

Shelf life after first opening the immediate package: 28 days

#### Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste

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

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

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

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

Package sizes: 10 ml, 50 ml

Shelf life: 2 years

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

#### For animal use only.

Prescription veterinary medicine.

To be administered exclusively by a veterinarian.

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

Marketing authorization number: 319/97 SPC: 2024-12-31





<sup>&</sup>lt;sup>2</sup> may lead to dryness of the cornea

<sup>&</sup>lt;sup>3</sup> may occur during emergence

# Morbital



Injection solution intended for dogs and cats (pentobarbital sodium 133.3 mg/ml, pentobarbital 26.7 mg/ml)

#### Composition

Each ml contains:

#### **Active substances:**

Pentobarbital sodium 133.3 mg Pentobarbital 26.7 mg

Clear, colourless solution.

#### **Target species**

Dogs, cats

#### Indications for use

Product intended for use in euthanasia of dogs and cats.

#### Contraindications

Not for intrapulmonary, intrapleural and intramuscular administration

Do not use for anaesthesia.

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

#### **Special warnings**

Special precautions for safe use in the target species:

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

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

Persons with known hypersensitivity to barbiturates should avoid contact with the veterinary medicinal product.

When handling the product, use caution to avoid direct contact. If inhaled, go to fresh air immediately. In case of contact with skin, wash the affected area with soap and water and change clothes, if contaminated with the product. In case of contact with eyes, wash immediately with plenty of water and consult a physician. After ingestion, subcutaneous or intramuscular injection, the product begins to be rapidly absorbed. In case of ingestion or parenteral administration, always seek medical advice immediately and show the package leaflet to the physician. Due to possible sedation, difficulty breathing and blood pressure fluctuations, the person exposed to the product should not drive motor vehicles and always stay under care of others.

#### To the physician

Pentobarbital concentration in the product is high enough to produce a serious effect on the central nervous system in an adult after injection or ingestion of 2.5 ml of the product. One gram of pentobarbital (which corresponds to less than 7 ml of the product) may be lethal for humans. In case of exposure to the veterinary medicinal product, symptomatic treatment should be applied in order to sustain the basic vital signs.

#### Other precautions:

Consumption of meat from animals euthanised using this product is dangerous. It may result in deep anaesthesia or death. This also applies to heat treated meat, as barbiturates are resistant to high temperatures. For this reason, carcass of euthanised animals must not be destined for ingestion by other animals, but they should be disposed of in accordance with applicable regulations.

#### Pregnancy:

If used in pregnant bitches and queens, the death of the mother causes the death of the foetus.

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

Barbiturates enhance the inhibitory action of d-tubocurarine and hexamethonium on neurotransmission in the motor end plate. What is more, pentobarbital and streptomycin interact to induce significant vasodilation, mainly of kidney vessels. Intravenous injection of calcium solution cancels vasodilating effect, allowing the use of sodium pentobarbital in animals treated with streptomycin. Interactions with some aminoglycosides have also been confirmed.

#### Overdose:

Not applicable.

Special restrictions for use and special conditions for use:

For administration only by a veterinarian.

#### Major incompatibilities:

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

#### Adverse events

Frequency unknown (cannot be determined on the basis of available data):	Agitation.¹ Dyspnoea.

<sup>1</sup> Transient reaction.

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

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

Intravenous injection is the recommended route of administration.

Intraperitoneal administration is allowed when intravenous injection is impossible or dangerous.

Intracardiac administration is allowed only upon prior

elimination of pain or loss of

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

consciousness.

In case of rapid administration (preferably intravenous), the animal falls asleep without any adverse effects. Respiratory and cardiac arrest occur within a dozen or so seconds. Corneal reflex may persist for up to 90 seconds.





# Morbital



## Injection solution intended for dogs and cats (pentobarbital sodium 133.3 mg/ml, pentobarbital 26.7 mg/ml)

#### Dosage:

	Morbital	Pentobarbital natrium	Pentobarbital
Intravenous administration	0.3-0.6 ml/kg b.w.	39.99–79.98 mg/kg b.w.	8.01-16.02 mg/kg b.w.
Intraperitoneal administration	1.0-2.0 ml/kg b.w.	133.3-266.6 mg/kg b.w.	26.7-53.4 mg/kg b.w.
Intracardiac administration	0.3-0.6 ml/kg b.w.	39.99–79.98 mg/kg b.w.	8.01-16.02 mg/kg b.w.

#### Advice on correct administration

The preferred route of administration, involving the smallest and shortest possible pain, is intravenous injection.

In case when intravenous administration is impossible or dangerous, intraperitoneal administration is allowed. This route of administration allows for slow induction of sedation and anaesthesia in animals, therefore they should be provided with peace and quiet.

In fearful, aggressive or wild animals, premedication is recommended. Intracardiac administration is allowed only in exceptional cases, that is in fully sedated, unconscious and deeply anaesthetised animals.

The product should be injected at a fixed pace, with optimum doses administered rapidly. Administration of a deficient dose may induce signs of prolonged sleep with potential awakening.

Before the procedure, animal body weight should be determined as accurately as possible. Smaller doses per 1 kg of body weight are more effective in adult, ill and starving dogs.

In any case, make sure that death of an animal has been obtained indeed, as deep anaesthesia may give the appearances of death.

#### Withdrawal period(s)

Not applicable.

#### **Special storage precautions**

Keep out of the sight and reach of children.

Store below 25°C.

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

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

#### Special precautions for disposal

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

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

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

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

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

#### **Contact details**

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

Biowet Puławy Sp. z o.o.

Henryka Arciucha 2

24-100 Puławy

Poland

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

e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:

Biowet Puławy Sp. z o.o.

Henryka Arciucha 2

24-100 Puławy

Poland

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

e-mail: biowet@biowet.pl

Pack size: 100 ml

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

Marketing authorisation number: 651/99 SPC: 2024-11-26





## Morbital Plus



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

#### Composition

Each ml contains:

#### **Active substance**

Pentobarbital sodium 400 mg

(which corresponds to 364.6 mg of pentobarbital)

**Excipients:** 

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

Clear, blue solution.

#### **Target species**

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

#### Indications for use

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

#### **Contraindications**

Do not use for anaesthesia.

#### **Special warnings**

None

Special precautions for safe use in the target species:

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

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

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

Do not administer the product per os.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

While administering the product, use impermeable protective gloves.

#### To the physician:

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

#### Other precautions:

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

#### Pregnancy and lactation:

The product can be used in pregnant and lactating animals. <u>Interaction with other medicinal products and other forms of interaction:</u>

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

Premedication with sedatives, due to impaired circulation,

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





## Morbital Plus



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

Overdose: Not applicable.

Special restrictions for use and special conditions for use:

None

Major incompatibilities:

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

#### Adverse events

Minor muscle contractions may be observed in the animal after administration of the veterinary medicinal product. When an intravenous injection is not properly administered into a vein or the product is injected to organs with reduced absorption capabilities, death may be delayed. Barbiturates may produce an irritating effect in case of perivascular administration.

Pentobarbital sodium may cause animal agitation. Premedication/sedation significantly reduces the risk of agitation.

At times, after cardiac arrest, agonal respiration may be observed in the animal. At this stage, the animal is dead in clinical terms.

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

https://smz.ezdrowie.gov.pl

### Dosage for each target species, routes and method of administration

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

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

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

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

Intravenous injection should be the preferred method of administration. In necessary, before administration of the veterinary medicinal product, a proper sedative should be used. In case of cattle and horses, premedication is compulsory.

In case intravenous administration is problematic, intracardiac injection may be applied only after prior use of deep sedation or anaesthesia.

In small animals, intraperitoneal administration is allowed, but must be preceded by proper sedation. In pets, pentobarbital should be administered at a fixed pace until loss of consciousness is acknowledged.

In horses and cattle, pentobarbital must be administered as a rapid injection.

#### Advice on correct administration

Do not administer the product with visible signs of deterioration.

#### Withdrawal period(s)

Not applicable.

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

#### **Special storage precautions**

Store in the original package.

Store below 25°C.

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

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

Package size: 100 ml Shelf life: 2 years

#### To be administered exclusively by a veterinarian. Prescription 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





### Every day matters

### support during cancer treatment

# NeoplasmaVET

Capsules for dogs supporting nutrition during cancer treatment





- trans-resveratrol a natural polyphenol that helps protect cells against carcinogenic factors
- quercetin a natural flavonoid with strong antioxidant properties
- vitamin E and selenium enhance natural immunity by supporting T-lymphocyte activity

#### Composition

Plant-derived ingredients:

Japanese Knotweed (Polygonum cuspidatum)
Japanese Pagoda Tree (Sophora japonica L.)

**Dietary additives:** 

3a700/Vitamin E – 18,248 mg/kg

3b801/Sodium selenite – 67 mg/kg

Technological additives (emulsifiers):

1c322/Lecithin - 182,482 mg/kg

Technological additives (anti-caking agents):

E 551b/Colloidal Silica – 54,745 mg/kg

Sensory additives (capsule shell components):

E172/Yellow Iron Oxide - 3,026 mg/kg

E132/Indigotine – 1,316 mg/kg

**Analytical Constituents** 

Crude fat 17.84%, Crude ash, 7.72%, Crude protein 1.55% Phosphorus 0.5%, Crude fiber, Sodium <1.0%, Calcium <1.0%

#### **Properties and indications**

NeoplasmaVET supplements the diet of dogs with ingredients that strengthen the body and improve the quality of life of sick animals. Japanese Knotweed contains **transresveratrol**, a natural polyphenol that helps protect cells from carcinogenic factors. It positively impacts the circulatory system by improving microcirculation. Japanese Pagoda Tree contains **quercetin**, a powerful natural flavonoid with antioxidant properties, helping protect cells from the harmful effects of oxygen-free radicals. **Selenium** is a component of enzymatic proteins that protect cells from oxidative stress. **Vitamin E** and **selenium** enhance the natural immune response by supporting the activity of T lymphocytes, which

play a crucial role in the immune system's defense mechanisms.

NeoplasmaVET is recommended for dogs:

- Predisposed to cancer
- Diagnosed with cancer
- Undergoing palliative care to improve their quality of life

#### Dosage

1 capsule per 10 kg of body weight per day. The contents of the capsule should be mixed with food or administered directly into the mouth.

It is recommended to use NeoplasmaVET under the guidance of a veterinarian.

#### Storage conditions

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

#### Package size:

40 openable capsules (350 mg per capsule)

Shelf life: 2 years

#### Complementary feed for dogs.

Veterinary identification number: 06148301 Leaflet preparation date: 2024-10-24



### support during cancer



# NeoplasmaVET amino

Capsules for cats supporting the body during cancer



- trans-resveratrol and quercetin inhibit the development of cancer cells
- quercetin and taurine have strong antioxidant properties
- vitamin E and selenium support T-lymphocyte activity
- **amino acids** and lecithin stimulate the immune system

#### Composition

Plant-derived ingredients:

Japanese knotweed (Polygonum cuspidatum) Japanese pagoda tree (Sophora japonica L.)

Dietary additives/Vitamins per kg:

3a370/Taurine – 95,837 mg

3a700/Vitamin E - 8,440 mg

Dietary additives/Amino acids per kg:

3c451/L-glutamine – 159,729 mg

3c361/L-arginine - 143,756 mg

Dietary additive/Trace element compound per kg:

3b801/Sodium selenite - 43.8 mg

Technological additive/Emulsifier per kg:

1c322/Lecithin - 63,892 mg

Technological additive/Anti-caking agent per kg:

E 551b/Colloidal silica – 31,946 mg

Capsule shell ingredients:

Porcine-bovine gelatin

Sensory additive per kg:

E172/Red iron oxide - 20,000 mg

**Analytical Constituents** 

Crude protein -61.4%, Crude fat -1.6%, Crude fiber -<0.3%, Crude ash -4.2%, Moisture -5.4%

#### **Properties**

**Trans-resveratrol** and **quercetin** are polyphenols that help protect cells from carcinogenic factors. **Trans-resveratrol** derived from Japanese knotweed supports cardiovascular function by improving microcirculation. **Quercetin** from the Japanese pagoda tree and **taurine** have strong antioxidant properties, protecting the body against the harmful effects of

free radicals. **Vitamin E** and **selenium** enhance natural immunity by supporting T-lymphocyte activity, which plays a key role in the body's immune response. **Amino acids** and **lecithin** stimulate the immune system to combat oncological disease

#### Indications

- Supportive therapy in oncological disease
- During post-oncological treatment recovery to improve quality of life
- For breeds predisposed to cancer

#### Dosage and administration

1 capsule once daily. The capsule contents may be mixed with other food.

If the diet consists exclusively of dry food, slightly moisten the kibble to ensure the powder adheres to the food and is fully consumed.

NeoplasmaVET amino should preferably be used after consultation with a veterinarian.

#### Storage conditions

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

#### Package size:

40 openable capsules (389 mg per capsule)

Shelf life: 2 years

#### Complementary feed for cats.

Veterinary identification number: 06148301 Leaflet preparation date: 2024-10-24



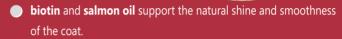
from the bottoms of the paws to the tip of the tail

complete care in a twist-off.



Twist-off capsules for dogs and cats. supporting skin and coat condition (biotin, zinc, fish oil, vitamins A, E,  $B_1$ ,  $B_6$ , i  $B_{12}$ )





- zinc and B vitamins help maintain healthy skin, reducing flaking, itching, and irritation.
- salmon oil provides essential fatty acids (EFAs) that nourish the skin from within and strengthen the coat's structure.
- $\bigcirc$  vitamins A, E, B<sub>1</sub>, B<sub>6</sub> and B<sub>12</sub> support skin regeneration, improve cellular metabolism, and protect against oxidative stress.
- easy application the convenient twist-off capsule form allows the product to be administered directly into the mouth, onto food, or applied to the paw for licking.

#### Ingredients:

fish oil, calcium carbonate, magnesium oxide

#### Additives and vitamins:

vitamins A, B1, B6, B12, and E, biotin, zinc oxide, soy lecithin

#### **Analytical constituents:**

zinc, magnesium, potassium, sodium, calcium, iron

#### **Properties and Indications**

Olderm contains a complex of vitamins and salmon oil, which is a source of essential unsaturated fatty acids (EFAs) beneficial for skin and coat condition. Fatty acids support the function of the hydrolipid barrier of the epidermis, helping to prevent excessive water loss. Zinc aids in the skin regeneration process. Biotin reduces excessive oiliness of the skin. Vitamin E has antioxidant properties, protecting the coat from environmental damage. Vitamin A supports proper growth and differentiation of epidermal cells. Vitamins B<sub>1</sub>, B<sub>6</sub>, and B<sub>12</sub> are involved in the metabolism of omega-type fatty acids. The product strengthens the skin's protective barrier and the body's natural immunity, improves the quality, strength, and density of hair, and shortens the shedding period.

#### Olderm is recommended:

- In cases of hair loss and increased hair fragility
- As a supportive treatment for dermatological disorders (genetic or allergic dermatoses)
- For dry skin

- For excessive flaking of the skin
- In diets lacking essential nutrients
- During shedding season or after pregnancy

- Up to 15 kg body weight: one capsule daily
- · Over 15 kg body weight: two capsules daily







The capsule can be given whole, directly or mixed with food. Alternatively, twist and remove the tip of the capsule and administer the contents directly into the mouth, on the paw, or mixed with food.

Package size: 60 twist-off capsules

Complementary feed for dogs, cats, and small furry animals.

Leaflet preparation date: 2025-04-07



just a moment to care for your pet's health



Ear care product for dogs and cats





- softens and dissolves earwax
- facilitates the penetration of active substances
  - from medications
- soothes and reduces itching
- cleans and cares for the ears

#### Composition

Xylene, glycerin, menthol, thymol, and propylene glycol.

#### **Properties and action**

Xylene, due to its cerumenolytic action, ensures excellent solubility of earwax. Glycerin and propylene glycol, with their softening and soothing properties, facilitate the penetration of active substances and provide excellent tolerance of the solution. Glycerin also has strong dissolving properties.

Menthol and thymol combine antiseptic and dehydrating properties (imparting fragrance). The combination of these properties makes OTICLAR an excellent ear care product for dogs and cats.

#### **Indications**

OTICLAR can be used for regular ear hygiene in dogs and cats, once or twice a week. In ear diseases, it is typically used for the initial cleaning of the ear canal before applying the appropriate therapeutic agent, as an excessive amount of earwax may reduce the effectiveness of the primary treatment.

#### Instructions for use

For external use in the ears.

Introduce a few milliliters of the solution into the ear canal and clean, repeating the procedure until the ear is fully cleaned. If earwax production is excessive, the product can be

used once daily for two or three consecutive days without the risk of complications. In dogs (especially those with floppy ears) suffering from chronic otitis externa, daily use of the product can help achieve faster improvement.

#### **Contraindications**

Do not use in cases of inner ear infections.

In cases of otitis externa, use the product for initial cleaning before applying the appropriate treatment.

Do not use in animals with skin hypersensitivity to the ingredients (allergy).

#### Storage conditions

Store at a temperature not exceeding 25°C. Keep out of sight and reach of children.

Package size: 50 ml bottles

Shelf life: 2 years

#### For animal use only.

Leaflet preparation date: 2013-10-25



# Oxytocinum Biowet Puławy



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

#### **Active substance and excipient content**

1 ml contains:

#### **Active substance:**

oxytocin 10 IU

#### **Excipient:**

chlorobutanol hemihydrate

#### Therapeutic indications

Stimulation of uterine contractions to induce labour.

Support of involution of the uterus after labour.

Increasing contractility of the myometrium after labour in order to prevent haemorrhage and retained placenta.

Induction of milk letdown in the case of postpartum dysgalactia.

#### **Contraindications**

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

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

#### Adverse reactions

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

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

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

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

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

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

cattle, horses: 3-5 ml (which corresponds to 30-50 IU), pigs, sheeps: 2-3 ml (which corresponds to 20 - 30 IU), 0.5-1.5 ml (which corresponds to 5 – 15 IU), dogs: 0.3-0.5 ml (which corresponds to 3-5 IU). cats:

In justified cases, the product can also be administered intravenously. However, reduction of the dose to approx. 1/4 of the recommended dose for other routes of administration is advised. Administer in an infusion or a slow injection (having diluted it in physiological saline) after the product has been warmed to body temperature.

If necessary, the injection can be repeated, but not sooner than after 30 minutes.

#### Indications for proper administration

None

#### Withdrawal period

Edible tissues

Cattle, horses, swine, sheep – zero days.

Milk

Cattle, sheep – zero hours

Dogs, cats – not applicable.

#### Special precautions for storage

Keep out of the reach and sight of children.

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

Do not freeze.

Protect from light.

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

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

#### **Special warnings**

Special warnings per target species:

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

Special precautions for use in animals:

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

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

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

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

#### Pregnancy and lactation:

Oxytocin is used to increase uterine contractions during labour and in lactation in

order to empty the mammary gland of milk or inflammatory secretion.

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











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

<u>Interactions with other medicinal products and other forms of interaction:</u>

Interaction between oxytocin and insulin and glucagon leads to an increase in the concentration of glucose.

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

The result of administration of too high a dose of oxytocin may be a long-lasting uterine contraction in concomitance with hypoxia in foetuses or metrorrhexis. Tachycardia may occur.

The effect of oxytocin is removed by beta-adrenomimetics (e.g. clenbuterol, bamethan) and progesterone.

Pharmaceutical incompatibilities:

Oxytocin displays pharmaceutical incompatibility with the following substances: warfarin sodium, fibrinolysin, epinephrine bitartrate and prochlorperazine edisylate.

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

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

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

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

For animal treatment only.
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









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

#### Composition

Each ml contains:

#### Active substances:

Sulfadimidine sodium – 50 mgSulfacetamide sodium – 40 mg

Sulfathiazole sodium – 30 mg  $\,$ 

#### **Excipient:**

chlorocresol – 2 mg Brown solution.

#### **Target species**

Horses, cattle, pigs, sheep, dogs.

#### Indications for use

#### Horses:

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

#### Cattle:

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

#### Sheep:

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

#### Pigs:

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

#### Dogs:

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

#### Contraindications

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

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

Do not use in pregnant and very young animals.

#### **Special warnings**

#### Special warnings:

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

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

Sulphonamides are less efficient in purulent drainage and necrotic tissues.

#### Special precautions for safe use in the target species:

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

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

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

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

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

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

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

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

#### Pregnancy:

Do not use during pregnancy.

#### 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<sup>®</sup>



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<sup>1</sup>, fever<sup>1</sup>
- collapse<sup>3</sup>, anaphylaxis<sup>1</sup>
- difficulty passing urine, cloudy urine, hematuria<sup>1</sup>, crystalluria, renal tubular obstruction
- swelling at the injection site<sup>2</sup>, skin lesions<sup>1</sup>, hives (urticaria)<sup>1</sup>
- ataxia<sup>3</sup>, muscle weakness<sup>3</sup>
- arthritis¹
- haemolytic anemia<sup>1</sup>, agranulocytosis<sup>1</sup>
- blindness<sup>3</sup>
- gastrointestinal tract disorders<sup>4</sup>
- <sup>1</sup> May occur in animals with hypersensitivity to sulphonamides.
- <sup>2</sup> May occur after intramuscular or subcutaneous administration.
- <sup>3</sup> May occur in case of rapid intravenous injection.
- <sup>4</sup> 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  $\frac{1}{2}$  of the initial dose.

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

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

#### Advice on correct administration

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

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

When administered intravenously, inject the product slowly.

#### Withdrawal period(s)

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.

Pias:

Meat and offal - 10 days

Dogs: not applicable

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

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

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

#### **Special storage precautions**

Keep out of the sight and reach of children.

Store in a refrigerator (2°C-8°C).

Protect from light. Do not freeze.

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









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

stated on the label after EXP. The expiry date refers to the last day of that month.

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

#### Special precautions for disposal

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

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

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

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

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

#### **Contact details**

Poland

Marketing authorisation holder and manufacturer responsible for batch release:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy

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

e-mail: sekretariat@biowet.pl

Contact details to report suspected adverse events:

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

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

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









### 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

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

In the case of intravenous administration, the preparation should be warmed to body temperature and injected slowly. In order to determine appropriate dosage, the animal's body weight should be measured as accurately as possible.

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

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

#### Instructions for use

None

#### Withdrawal period

Cattle and horses:

edible tissues - zero days,

milk – zero days.

Dogs and cats - not applicable.

#### Special warnings and precautions

Special precautions for use in animals:

#### Horses:

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

#### Cats and dogs:

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

#### Cattle:

- Under the influence of xylazine, motility of the forestomachs decreases, which may lead to flatulence. Therefore, it is recommended that the animals should not be fed or watered for several hours before administration of xylazine,
- Xylazine weakens reflexes of belching, couching and swallowing. Therefore, cattle must be observed carefully while they are regaining consciousness and must remain in a sternal position,
- In cattle, administration of low and medium doses is recommended.









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

Avoid administering too high doses of the drug. Adjust dosage considering individual sensitivity of each animal.

Exercise particular caution when using the drug in convulsions, acute renal or hepatic insufficiency and in dehydrated animals.

In order to prevent choking on saliva or vomit, the animal's head should be positioned lower than the rest of the body.

Old and fatigued animals may be more sensitive to the effect of xylazine whereas agitated animals may require higher doses.

During the use of the product, peace should be provided for patients because external stimuli may deteriorate reaction to the product.

Xylazine may impair thermoregulation. If ambient temperature differs from room temperature, cooling or warming the patient is recommended during the use of the product.

In the case of painful procedures, xylazine should be used in combination with local or general anaesthesia.

Treated animals should be monitored until the effects of the product subside completely. During this time, they should be kept in a separate room in order to avoid injuries from other animals.

Drugs with a central neurodepressive effect (anaesthetics, analgesics) boost the effect of xylazine. Intensification of the cardiodepressive effect, weakening of respiratory action and hypotensive effect occurs. Therefore, the combination of xylazine and opioids is used with great caution.

Xylazine should not be combined with thiobarbiturates and halothane due to the consequent intensification of cardiac arrhythmia.

Due to the risk of ventricular arrhythmia, xylazine should not be combined with adrenaline and other drugs stimulating the sympathetic nervous system or used immediately after their administration.

Do not use xylazine in advanced pregnancy because it may lead to miscarriage.

In overdose, adverse effects are intensified: there is a risk of respiratory arrest and collapse; convulsive seizures may occur. Partial elimination of the effect of xylazine may be obtained by administration of central antagonists of  $\alpha 2\text{-}adrenergic$  receptors: yohimbine in the dose of 0.1 – 0.2 mg/kg b.w. intravenously or tolazoline in the dose of 0.5 – 1.0 mg/kg b.w. intravenously.

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

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

If the product is accidentally swallowed or self-injected, immediately seek medical advice and show the package leaflet to the physician, but do not drive due to the possibility of sedation and changes in the arterial blood pressure.

Avoid contact with skin, eyes and mucosa.

In the case of contact of the product with bare skin, wash the skin with plenty of water immediately.

Remove contaminated clothing being in direct contact with the skin.

If the product has accidental contact with an eye, wash the eye with plenty of water. In the case of any symptoms, you should contact a physician.

If a pregnant woman administers the medicinal product, she should take special precautions to prevent self-injection due to the possibility of the occurrence of uterine contractions and reduced foetal arterial blood pressure after accidental general exposure.

#### Indications for physicians

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

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

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

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

Package sizes: 20 ml and 50 ml

Shelf life: 2 years

For animal treatment only.

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









Openable capsules for cats and small breed dogs supporting urinary tract function (L-methionine, vitamins  $\mathbb{C}$  and  $\mathbb{D}_3$ , colostrum)





- lowers urine pH
- prevents recurrent bladder and urethral infections



#### Composition per capsule:

bovine colostrum (Colostrum bovinum) > 60% Dietary additive / Amino acid per kg: 3c305 / L-methionine 666,622 mg Dietary additives / Vitamins per kg: 3a300 / Vitamin C 166,656 mg 3a671 / Vitamin D<sub>3</sub> 30,400 IU

Technological additive / Anti-caking agent per kg:

 $E\,551b\,/\,colloidal\,silica\,83,\!328\,mg$ 

Capsule shell:

porcine-bovine gelatin

Sensory additives per kg:

E172 / yellow iron oxide 3,000 mg  $\,$ 

E132 / indigo carmine 1,300 mg

Analytical constituents:

crude protein 58.6%, crude ash 5.9%, crude fat < 1.0%, crude fiber < 0.3%, moisture 4.1%

#### **Properties:**

The amino acid **L-methionine** supports the dissolution of struvite stones by lowering urine pH. **Vitamin D**<sub>3</sub> enhances calcium and phosphate absorption and balance in the kidneys. It also contributes to proper immune system function. **Vitamin C** protects cells from free radical damage and aids in urine acidification. **Colostrum** contains immunoglobulins that support the immune system.

#### Indications:

- As an adjunct in the treatment and prevention of struvite urolithiasis.
- For prophylactic use in recurrent urinary bladder and urethral infections.
- To promote urine acidification.

#### **Administration:**

1 capsule twice daily.

The capsule contents may be mixed with other food. If the animal is fed exclusively with dry food, slightly moisten the food so that the powder adheres and is fully consumed. Do not use in combination with other urine acidifying diets.

 $Uromet in should \ be \ used \ under \ veterinary \ supervision.$ 

#### Storage conditions:

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

Packaging size: 40 openable capsules (376 mg per capsule)

#### Complementary feed for cats and small breed dogs.

Veterinary identification number: 06148301 Leaflet preparation date: 2024-10-24





### support bladder health

### more joy with every step

# **Urometin** forte

Sprinkle capsules for medium and large breed dogs supporting urinary tract function (L-methionine, vitamins C and  $D_3$ , colostrum)





- vitamin D<sub>3</sub> improves absorption and balances calcium-to-phosphate ratio in the kidneys
- colostrum supports the body's immune system
- vitamin C helps acidify the urine
- brewer's yeast is a natural source of B vitamins









#### Composition per Capsule

bovine colostrum (Colostrum bovinum) > 60% brewer's yeast from Saccharomyces cerevisiae – 50 mg Dietary Additives / Amino Acids per kg: 3c305 / L-Methionine 677,932 mg

<u>Dietary Additives / Vitamins per kg:</u> 3a300 / Vitamin C 101,690 mg 3a671 / Vitamin D, 21,700 IU

Technological Additives / Anti-Caking Agent per kg:

E 551b / colloidal silica 67,797 mg

Capsule Shell:

porcine-bovine gelatin

Sensory additives per kg:

E172 / red iron oxide 20,000 mg

Analytical Constituents

crude protein: 56.3%, crude ash: 6.15%, crude fat: < 1.0%,

crude fiber: < 0.3%, moisture: 3.7%

#### **Properties**

The amino acid L-methionine helps dissolve struvite stones by lowering urine pH. Vitamin  $D_3$  enhances calcium and phosphate absorption in the kidneys and supports immune system function. Vitamin C protects cells from free radical damage and aids in urine acidification. Colostrum contains immunoglobulins that support the immune system. Brewer's yeast is a natural source of B vitamins.

#### Indications

- Supportive treatment and prevention of struvite urolithiasis;
- $Prevention \, of \, recurrent \, bladder \, and \, ure thral \, in fections;$
- Urine acidification

#### Dosage and administration

- Dogs 10-25 kg: 2 capsules once daily
- Dogs > 25 kg: 3 capsules once daily

The capsule contents may be mixed with other food. If the diet consists solely of dry food, lightly moisten it to ensure powder adherence and consumption.

Do not use in combination with other urine acidifying feeds. Urometin Forte should preferably be used after consulting a veterinarian.

#### Storage conditions

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

Package size: 40 openable capsules (708.03 mg per capsule)

#### Complementary feed for medium and large breed dogs.

Veterinary identification number: 06148301 Leaflet preparation date: 2024-10-24







### Injection solution intended for dogs, cats and foxes (flumethazone 0,5 mg/ml)

#### Composition

Flumethasone 0.5 mg / ml

#### Indications

The medicine is intended to be used in the course of:

- · rheumatoid conditions.
- allergy and inflammation related dermatological conditions,
- · muscle, joint and tendon inflammation,
- · respiratory system disorders and mastitis.

#### **Contraindications**

Hypersensitivity to flumethasone or any of the components of the product.

General contraindications for the use of glucocorticosteroids also apply to Vecort.

Do not use the drug in cases of: stomach and intestinal ulcers, viral infections, systemic mycoses, pregnancy, hypocalcaemia, osteoporosis, cataracts, glaucoma, poorly healing wounds. Vecort should not be used in the case of bacterial infections

#### Adverse reactions

Like all medicines, Vecort can cause adverse reactions.

until an effective antibiotic therapy has been applied.

An increased demand for water, polyuria and increased appetite may occur.

Stomach and intestinal ulcerations, osteoporosis, growth retardation in young animals may occur. Glucocorticosteroids can cause reversible damage to the liver, hypertension, increased risk of thrombosis, development of cataract, prolonged wound healing.

In long-term treatment with glucocorticosteroids, iatrogenic Cushing's syndrome may occur. Long-term glucocorticosteroid therapy may cause immunosuppression.

A prolonged use of the drug leads to a decrease in adrenal cortex activity and may even lead to atrophy.

Administration of glucocorticosteroids may affect the results of blood laboratory tests causing: increased activity of alkaline phosphatase, increased glucose concentration, decreased concentration total and free  $T_{4\prime}$  leucocytosis. Glucocorticosteroids affect the results of tests that assess the activity of the hypothalamo-pituitary-adrenal system and the results of allergic skin tests.

The occurrence of adverse reactions after the administration of this product, or any observed symptoms that cause worry not mentioned in the leaflet (including human reactions due to contact with the medicine), must be reported to a competent veterinarian, the holder of the authorisation or the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products. A notification form is to be downloaded at https://www.urpl.gov.pl (Veterinary Medicinal Products Division).

#### **Target species**

Dog, cat, fox

#### Dosage and route of administration

Small and medium size dogs, cats, foxes:

0.25 - 0.5 ml intravenously, intramuscularly, subcutaneously 0.25 - 0.5 ml intra-articularly

#### Large dogs:

0.5 – 1 ml intravenously, intramuscularly, subcutaneously 0.25 – 0.5 ml intra-articularly

The product is administered once; in justified cases, the dose may be repeated after 3 days.

#### Advice on correct administration

Not applicable.

#### Withdrawal period(s)

Not applicable.

#### Special precautions fot storage and transport

Keep this medicine out of sight and reach of children.

Do not store above 25°C. Protect from light.

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

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

#### Special warnings and precautions, if necessary

Special warnings for each target species:

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

<u>Special precautions for persons administering the veterinary medicinal product to animals:</u> Protect eyes before being exposed to the product.

In case of accidental self-injection, immediately seek doctor's advice and present the doctor with the information leaflet or package.

#### Pregnancy and lactation:

Do not use during the whole or part of the pregnancy and in lactating females.

Interaction with other medicinal products and other forms of interaction

Glucocorticosteroids administered in combination with cholinesterase inhibitors may cause increased muscle weakness. Administrated with anticoagulants may reduce or increase their effect. Administered with diuretics and amphotericin B, they may increase the risk of hypokalemia. Used in combination with ephedrine, estrogens, ketoconazole and macrolide antibiotics may intensify and prolong the activity of glucocorticosteroids. Administered together with phenobarbital, phenytoin and rifampicin may weaken the effect of glucocorticosteroids. Glycocorticosteroids weaken the effect of insulin. The combined use of theophylline and glucocorticosteroids changes the activity of both drugs. Glucocorticosteroids should not be used in combination with non-steroidal anti-inflammatory drugs because of the increased risk of gastric ulceration. Glycocorticosteroids increase the risk of

poisoning with drugs such as cyclosporine, erythromycin or cardiac glycosides. The use of glucocorticosteroids should be avoided with vaccines containing live attenuated viruses, as this may lead to increased virus replication.











### Injection solution intended for dogs, cats and foxes (flumethazone 0,5 mg/ml)

Overdose (symptoms, emergency procedures, antidotes):

Overdose may cause a decrease in immunity and, consequently, a growing risk of bacterial, fungal and viral infection.

Multiple high doses of glucocorticosteroids may lead to the occurrence of iatrogenic Cushing syndrome (polyuria, polydypsia, polyphagia, truncal obesity, liver enlargement, saggy stomach, hair loss – often symmetrical, thinning of the skin and visible vessels – especially on the abdomen, excessive pigmentation, skin calcifications, muscle weakness and atrophy). Sudden discontinuation of glucocorticosteroids after prolonged treatment (more than 2 weeks) may cause glucocorticosteroid withdrawal syndrome (Addison's disease).

### Special precautions fot the disposal of unused veterinary medicinal products or waste materials from the product if applicable

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

Ask your veterinary surgeon how to dispose of unusable medicines. They will ensure better environmental protection.

#### Other information

For any information about this veterinary medicinal product, please contact the marketing authorisation holder.

#### **Available containers:**

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

Shelf lie: 2 years

For animal use only.

Prescription veterinary medicine.

To be administered under veterinary supervision.

Marketing authorization number: 951/99 SPC: 2017-10-24





professional support in the treatment

of urinary tract diseases



Capsules for cats and small breed dogs supporting urinary tract function

(cranberry, glucosamine, vitamin C, bovine colostrum)





- Aids in the treatment of urinary tract inflammations
- Improves the quality of life for animals with urinary tract disorders
- Lowers urine pH

#### Composition per capsule:

Products and co-products derived from the processing of fresh fruits and vegetables:

Cranberry (Vaccinium macrocarpon) – 90 mg

Glucosamine (from animal tissues) – 90 mg

Bovine colostrum (Colostrum bovinum) – 15 mg

Sensory additive per kg:

2b Green tea extract (source of L-theanine) – 42 g

Nutritional additive / Vitamin per kg:

3a300 Vitamin C – 167 g

Technological additive / Anti-caking agent:

E551b Colloidal silica

Capsule shell:

Porcine and bovine gelatin

Sensory additive: E172 Red iron oxide

Analytical constituents:

Crude protein: 32%, crude ash: 10.5%, crude fat: 14.8%, crude fiber: < 0.3%, moisture: 4.7%

#### **Properties:**

The active components of the product support urinary tract health and contribute to proper bladder function. Cranberry (Vaccinium macrocarpon) lowers urine pH, creating an unfavorable environment for bacterial proliferation. Glucosamine helps protect the bladder wall by reducing its permeability. Vitamin C supports the immune system and acts as a potent antioxidant. Bovine colostrum contains immunoglobulins that enhance immune function. L-theanine from green tea has a calming effect on the nervous system and helps reduce stress levels.

#### Indications:

- prophylactic support of urinary tract function
- adjunctive use in urinary tract inflammation
- in animals with urinary dysfunction to improve quality of life
- to assist in lowering urinary pH

#### **Directions for use:**

Administer 1 capsule daily.

The dose may be increased if necessary.

If needed, the capsule may be opened and its contents mixed with food

It is recommended to consult a veterinarian before use.

#### Storage conditions:

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

Clumping of the capsule contents may occur and does not affect the product's efficacy.

**Packaging size:** 40 openable capsules (436 mg per capsule)

Complementary feed for cats and small breed dogs up to

Veterinary identification number: 06148301 Leaflet preparation date: 2025-06-11





### support for urinary tract function

# Veturino forte

Capsules for medium and large breed dogs supporting urinary system function (cranberry, glucosamine, vitamin C, bovine colostrum)





- glucosamine reduces bladder permeability and provides a protective effect
- vitamin C supports the immune system and acts as an antioxidant
- **bovine colostrum** supports immune function
- L-theanine has a calming effect on the nervous system and reduces stress

#### Composition per capsule:

Products and by-products derived from fresh fruits and vegetables:

Cranberry (Vaccinium macrocarpon) – 200 mg Glucosamine from animal tissues – 190 mg Bovine colostrum (Colostrum bovinum) – 40 mg

Wheat starch

Sensory additive per kg:

2b Green tea extract (source of L-theanine) – 43 g

Nutritional additive / Vitamins per kg:

3a300 Vitamin C - 129 g

Technological additive / Anti-caking agent:

E551b Colloidal silica

Capsule shell:

Porcine and bovine gelatin

Sensory additive: E172 Red iron oxide

Analytical constituents:

Crude protein: 32.8%, crude ash: 6.6%, crude fat: < 1.0%, crude fiber: < 0.3%, moisture: 4.6%

#### **Properties:**

The ingredients in this product support urinary tract health and bladder function. **Cranberry** (*Vaccinium macrocarpon*) helps lower urine pH, creating an unfavorable environment for bacterial proliferation. **Glucosamine** exerts a protective effect on the bladder wall by reducing its permeability. **Vitamin C** supports the immune system and acts as a powerful antioxidant. **Bovine colostrum** contains immunoglobulins that enhance the body's immune response. L-theanine, derived from green tea, has a calming effect on the nervous system and helps reduce stress levels.

#### Indications for use:

- Prophylactic support of the urinary tract
- Adjunctive support in cases of urinary tract inflammation
- To improve quality of life in animals with impaired urinary tract function
- To help reduce urine pH

#### **Directions for use:**

Administer the capsule as directed below or as advised by a veterinarian:

Dogs weighing 10-25 kg: 1 capsule once daily

Dogs > 25 kg: 2 capsules once daily

The dose may be increased if necessary. If needed, the capsule may be opened and its contents mixed with food. Veturino Forte should preferably be used under veterinary supervision.

#### Storage conditions:

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

Clumping of the capsule contents may occur, which does not affect the efficacy or performance of the product.

Package size: 40 openable capsules (818 mg per capsule)

Complementary feed for medium and large breed dogs.

Veterinary identification number: 06148301 Leaflet preparation date: 2025-06-16



# Vitaminum B<sub>I</sub> 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<sub>1</sub> deficiency and avitaminosis:

- in carnivorous animals on raw fish diet
- in animals artificially nourished using glucose infusions,
- conditions of increased metabolism (fevers, pregnancy, lactation).

Treatment of the following conditions in target species:

- cattle, sheep, horses: reduced viability of newborns.
- dogs: inflammation and paralysis of peripheral nerves, rheumatoid arthritis, nervous form of canine distemper, muscle weakness and digestive disorders leading to vitamin B deficiency.
- chickens, turkeys: ataxia, spasms, paralysis, muscle atrophy, polyneuritis.

#### Contraindications

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

#### **Special warnings**

<u>Special precautions for safe use in the target species:</u>
Do not administer the product intravenously as this might cause an anaphylactic shock.

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

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

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

Special precautions for the protection of the environment: Not applicable.

Pregnancy and lactation:

Can be used during pregnancy and lactation.

Laving birds

The product can be used during the laying period.

Interaction with other medicinal products and other forms of interaction:

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

Do not use the product together with iron solutions. Avoid administering the drug in combination with plants with high thiaminase content as its excess causes decomposition of vitamin B<sub>1</sub>.

#### 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<sub>1</sub> 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

<u>ggs:</u>

turkeys – zero days

Milk:

cattle – zero days

sheep – zero days

dogs – not applicable.









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

#### Special storage precautions

Keep out of the sight and reach of children. Store below 25°C. Protect from light. Do not freeze. Store in a closed container.

Do not use this veterinary medicinal product after its expiry date given on the label. The expiry date refers to the last day of that month.

#### Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste

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

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

#### Contact details

e-mail: sekretariat@biowet.pl

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

Contact details to report suspected adverse reactions:

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

Poland

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

e-mail: biowet@biowet.pl

Pack size: 50 ml

For animal use only.

Prescription veterinary medicine.

To be administered under veterinary supervision.

Marketing authorization number: 969/00 SPC: 2023-11-17





# Vitaminum Biowet Puławy



Injection solution intended for horses, cattle, pigs, sheep, dogs, cats and foxes

#### (ascorbic acid 100 mg/ml)

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

Ascorbic acid adds to the effect of coumarin anticoagulants. It increases iron absorption. Flavonoid glycosides enhance the effect of vitamin  $\mathsf{C}.$ 

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

<sup>1</sup> 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 administ-

#### Advice on correct administration

In case of intravenous administration, warm the product to body temperature and inject slowly.









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#### 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:

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: 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







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