

BABEZAN® 4%, 12%

solution for injection

INSTRUCTIONS
on the use of Babezan® 4% and 12% solution for injection for the treatment and prevention of blood parasitic diseases in horses, cattle, sheep and dogs

Approved by The Deputy Head of the Rosselkhoznadzor N.A. Vlasov.
(Developer organization: NVT Agrovetzschita LLC, Moscow, Kolskaya str., 1, h. 1)

I. General information

Trade name of the drug: Babezan® 4% and 12% solution for injection (Babezan® 4% et 12% solution pro injectionibus).

International nonproprietary name: imidocarb.

Dosage form: solution for injection.

Babezan® 4% and 12% solution for injection contains in 1 ml as an active substance imidocarb dipropionate – 40 mg and 120 mg, respectively, and as auxiliary substances: benzalkonium chloride, polyvinylpyrrolidone high molecular weight and water for injection. In appearance, the drug is a transparent yellow solution. The shelf life of the drug, subject to storage conditions in the manufacturer's closed packaging, is 2 years from the date of production, after the first opening of the bottle – 28 days. It is prohibited to use the drug after the expiration date.

Babezan® 4% solution for injection is released packaged in 5, 10 and 100 ml in dark glass bottles; Babezan® 12% solution for injection is released packaged in 50, 100, 200 and 250 ml in dark glass bottles, 450 and 500 ml in dark glass bottles of the corresponding capacities that are sealed with rubber stoppers reinforced with aluminum caps. Bottles of 5 and 10 ml are packed individually in cardboard packs with instructions for use. Each unit of consumer packaging is provided with instructions for the use of the drug.

The medicinal product is stored in a closed manufacturer's packaging in a dry place protected from direct sunlight, separate from food and feed, at a temperature from 5 °C to 25 °C.

Babezan® 4% and 12% solution for injection should be stored in places inaccessible to children.

Unused drug is disposed of in accordance with the requirements of the legislation.

It is released without a prescription from a veterinarian.

II. Pharmacological properties

Babezan® 4% and 12% solution for injection refers to antiprotozoal drugs of the imidazoline group.

Imidocarb dipropionate, which is part of the drug Babezan® 4% and 12% solution for injection, is active against *Babesia bovis*, *Babesia ovis*, *Babesia bigemina*, *Babesia colchica*, *Babesia equi*, *Babesia divergens*, *Babesia canis*, *Babesia caballi*, *Babesia gibsoni*, *Francaella colchica*, *Theileria annulata*, *Theileria sergenti*, *Theileria mutans*, *Theileria orientalis*, *Theileria ovis*, *Theileria recondite*, *Theileria tarandirangiferis*, *Nuttallia equi*, *Anaplasma marginale*, *Anaplasma ovis*, and *Ehrlichia canis*.

The mechanism of the antiprotozoal action of imidocarb is associated with the suppression of the intake of inositol, necessary for the vital activity of the blood parasite, as well as with the violation of the formation and use of polyamines by parasites. After parenteral administration of the drug, the therapeutic concentration of imidocarb in the blood is reached after 18-24 hours and is maintained at the pyroplasmatic level for 4-6 weeks. Imidocarb dipropionate accumulates mainly in the kidneys and liver; it is excreted from the body mainly with urine. Babezan® 4% and 12% solution for injection, according to the degree of exposure to the body, refers to moderately dangerous substances (hazard class 3 according to GOST 12.1.007-76), in recommended doses does not have locally irritating, cumulative, embryotoxic and mutagenic properties.

III. Administration procedure

Babezan® 4% and 12% solution for injection is prescribed for therapeutic and prophylactic purposes to horses, cattle, sheep and dogs with blood parasitic diseases – acute, chronic and subclinical babesiosis, anaplasmosis and nuttalliosis, as well as with mixed invasions.

Contraindication for the use of the drug is an individual hypersensitivity of animals to the components of the drug (including in the anamnesis). It is forbidden to use the drug for 4 weeks after vaccination with a live vaccine against babesiosis or anaplasmosis.

For dogs, Babezan® 4% and 12% solution for injection is used for babesiosis for therapeutic purposes once subcutaneously at a dose of 4 mg of imidocarb per 1 kg of animal weight, which corresponds to 0.1 ml/kg of Babezan® 4% solution for injection or 0.03 ml/kg of Babezan® 12% solution for injection.

If babesia is detected in a blood smear a day after using the drug, it is re-administered at the same dose.

For preventive purposes, when clinical signs of babesiosis appear or within a week after moving animals to areas that are unfavorable for this disease, Babezan® 4% and 12% injection solution is used for dogs once in a therapeutic dose.

The protective effect after injection of the drug persists for 4 weeks.

For cattle, sheep and horses, Babezan® 12% solution for injection is used for babesiosis and nuttalliosis for therapeutic purposes once intramuscularly at a dose of 2.5 mg of imidocarb per 1 kg of animal weight, which corresponds to 2.0 ml of the drug per 100 kg of animal weight.

In the treatment of anaplasmosis and mixed blood parasitic diseases (anaplasmosis + babesioz), the dose is increased to 5 mg of imidocarb per 1 kg of animal weight, which corresponds to 4.0 ml of Babezan® 12% solution for injection per 100 kg of animal weight.

For preventive purposes, when attacked (or threatened with attack) by ticks carrying blood parasitic diseases, Babezan® 12% solution for injection is administered to animals once intramuscularly at a dose of 2.5 ml per 100 kg of animal weight (3 mg of imidocarb per 1 kg of animal weight).

The protective effect of the drug persists for 30-45 days, depending on the epizootic situation and the physiological state of the animal.

In case of overdose and/or increased individual sensitivity of the animal to the drug, complications may develop (bradycardia, increased frequency and respiratory disorders, anorexia, excessive salivation, lacrimation, sweating, muscle tremor, frequent urination and defecation), in these cases, a 1% solution of atropine is prescribed subcutaneously, symptomatic agents and desensitizing therapy is performed.

In rare cases, a local reaction is possible in the form of hyperemia or painful swelling at the site of administration of the drug, which disappears spontaneously after 1-2 days. Repeated administration may be accompanied by a decrease in blood pressure.

Due to a possible pain reaction, the drug should not be administered in one place to large animals in a volume exceeding 10 ml and to small animals in a volume exceeding 2.5 ml.

For puppies, pregnant and lactating females, the drug can be used after consultation with a veterinarian. Milk from lactating females of productive animals can be used for food purposes and for feeding offspring no earlier than the prescribed period.

The drug is intended for single use.

When using Babezan® 4% and 12% solution for injection according to this instruction, side effects and complications in animals, as a rule, not observed. In rare cases, hypersalivation, tremor of the abdominal wall muscles and a local reaction in the form of hyperemia or swelling at the injection site, which disappears after 1-2 days, is possible. With the mass death of blood parasites and destruction of erythrocytes after the use of Babezan® 4% and 12% solution for injection, intoxication may develop in animals. In this case, intensive therapy is necessary, including intravenous administration of electrolyte solutions and hepatoprotectors. It is advisable to use antihistamines for animals with clinical signs of babesiosis before the introduction of Babezan® 4% and 12% solution for injection.

Simultaneous use of Babezan® 4% and 12% solution for injection with organochlorine, organophosphate preparations and other cholinesterase inhibitors is not allowed.

Slaughter for cattle, sheep and horses is allowed no earlier than 28 days after the last application of Babezan® 4% and 12% solution for injection. The meat of animals forcibly killed before the expiration of the specified period can be used as fodder for fur-bearing animals.

Milk obtained from animals after the use of Babezan® 4% and 12% solution for injection is allowed to be used for food purposes no earlier than 4 days after the last administration of the drug. Milk obtained earlier than the prescribed period after boiling can be used in animal feed.

IV. Personal prevention measures

When working with Babezan® 4% and 12% solution for injection, the general rules of personal hygiene and safety provided for when working with medicines should be observed.

At the end of the work, hands should be washed with warm water and soap.

Empty drug packaging may not be used for household purposes and must be disposed of with household waste.

In case of accidental contact of the drug with the skin or mucous membranes of the eyes, they must be rinsed with plenty of water. People with hypersensitivity to the components of the drug should avoid direct contact with Babezan® 4% and 12% solution for injection. In case of allergic reactions or accidental ingestion of the drug into the human body, it is necessary to immediately contact a medical institution (have the instructions for use or label with you).

Registration certificate number: 77-3-4.16-3162NeVDR-3-5.0/02641



Name and address of the production site of the manufacturer of the drug product for veterinary use:

AVZ S-P, Russia, 141305, Moscow region, Sergiev Posad, Tsentralnaya str., 1.

Name, address of the organization authorized by the holder or owner of the registration certificate of the drug to accept claims from the consumer: AVZ S-P, Russia, 141305, Moscow region, Sergiev Posad, Tsentralnaya str., 1.

Phone number of the round-the-clock Hotline: 8-800-700-19-93 (toll-free call from Russia).

Information about the drug is available on the website www.avzvet.ru