

INSTRUCTIONS FOR USE

Piroteks B12 + B6

Diminazene diacetate

Pharmaceutical form

Granules for the preparation of a solution for injection.

Pharmacotherapeutic group

Antiparasitic, antiprotozoal agent. ATCvet code: QP51DF01 - diminazene.

Target species

Cattle, sheep and goats, camels, horses and dogs.

Composition

Each 1 g of granules contains the active substance: diminazene diacetate - 0.445 g.

Excipients: phenazone - 0.55246 g; vitamin B12 - 0.424 mg; vitamin B6 - 2.119 mg.

Description

Yellow to orange granules with a characteristic odour.

Presentation

1.57 g and 2.36 g granules for the preparation of a solution for injection, in dark glass vials, hermetically sealed with a rubber stopper, an aluminium cap and a plastic cap providing evidence of first opening.

Pharmacological properties

Diminazene diacetate is an antiprotozoal agent active against blood parasites: *Babesia* (*Babesia bovis*, *Babesia ovis*, *Babesia caballi*, *Babesia equi*, *Babesia canis*), trypanosomes (*Tr. congolense*, *Tr. vivax*, *Tr. brucei*) and *Theileria* (*Theileria annulata*). Its mechanism of action is based on inhibition of aerobic glycolysis and DNA synthesis in pathogenic protozoa.

Phenazone (antipyrine) stabilises diminazene and also has analgesic, antipyretic and anti-inflammatory effects, reducing the duration of fever.

Vitamins B6 and B12 support the normal functioning of the blood-forming organs and the nervous system.

Following parenteral administration of the solution, diminazene reaches a therapeutic blood concentration within 3-4 hours and maintains therapeutic levels for 24 hours. The medicine accumulates mainly in the kidneys and liver and is excreted in urine and, during lactation, partly in milk.

According to its degree of impact, Piroteks B12 + B6 is classified as a moderately hazardous substance (hazard class 3). At the recommended doses, it has no sensitising, embryotoxic or teratogenic effects.

Indications

Piroteks B12 + B6 is used for the treatment and prevention of blood-parasitic diseases in cattle, sheep, goats, horses, camels and dogs (trypanosomiasis, piroplasmosis, babesiosis, haemosporidiosis, francaiellosis, theileriosis and equine nuttalliosis), as well as mixed infestations (piroplasmosis and francaiellosis).

Method of administration and dosage

Preparation of the solution for injection: prepare a 7% solution for injection (diminazene diacetate 70 mg/mL) before use. Add 8.5 mL of water for injections to 1.57 g of Piroteks granules, or 12.5 mL of water for injections to 2.36 g of granules. For subcutaneous or intramuscular administration.

Treatment of piroplasmosis, babesiosis, francaiellosis and nuttalliosis

Cattle, sheep and goats, horses and dogs: 3.5 mg diminazene diacetate per kg body weight, or 1 mL of solution per 20 kg body weight, as a single administration.

Treatment of theileriosis

Cattle: 5 mg diminazene diacetate per kg body weight, or 7 mL of solution per 100 kg body weight, for 2 days, or 3-4 injections daily.

Treatment of trypanosomiasis

Cattle, horses and dogs:

T. congolense, *T. vivax*: 3.5 mg diminazene diacetate per kg body weight, or 1 mL of solution per 20 kg body weight, as a single administration.

T. brucei, *T. evansi*, *T. equiperdum*: 8 mg diminazene diacetate per kg body weight, or 1 mL per 10 kg body weight.

Trypanosomiasis in camels: 1.75 mg diminazene diacetate per kg body weight, or 1 mL per 40 kg body weight.

If the course of the disease is unfavourable, the injection may be repeated after 24 hours at the same dose. Additional symptomatic treatment is prescribed (cardiac agents, antihistamines, sedatives, vitamins and trace elements).

Prevention

For prevention (when protozoal diseases are detected and/or animals are moved into areas affected by protozoal diseases), administer 3.5 mg diminazene diacetate per kg body weight, or 1 mL of solution per 40 kg body weight. If necessary, the injection may be repeated after 10-15 days.

If the calculated volume exceeds 10 mL for large animals or 2.5 mL for small animals, or if a pain reaction occurs, the dose is administered at several sites.

Adverse reactions

When used at the recommended doses, the medicine causes no adverse reactions. In the event of overdose, animals may show nervous symptoms (bradycardia, increased respiratory rate, anorexia and tremor). In such cases, provide symptomatic treatment.

For dogs, parenteral administration of an antihistamine before administration of the medicine is recommended.

Contraindications

Hypersensitivity to any component of the medicine.

Withdrawal period

Meat - 21 days. Milk - 3 days.

Storage conditions

Store in a dry place, protected from light, at a temperature not exceeding 30 °C, out of the reach of children.

Veterinary use

For veterinary use.

Shelf life

3 years.

Manufacturer

Biotechs LLC, Georgia.