



Babesit

Injectable Solution
84,198mg/ml Imidokarb dipropiyonat



Cattle, Horse and Dogs Strong Protection and Treatment Against Babesiosis

Babesit is effective in preventing and treating the following blood parasites:

In cattle: Babesia argentina, B. bigemina, B. bovis, and B. divergens. Anaplasma marginale

In dogs: Babesia canis, B. gibsoni, and B. vogelli

In horses: Babesia equi and B. caballi



Single-dose protection

A single injection provides protection for 4 weeks



Fast effect

Plasma peak level is reached 1 hour after application.



Effective treatment with a single dose

In the fight against babesiosis, a single injection via intramuscular or subcutaneous administration is sufficient. (In horses, the number of doses varies depending on the clinical picture.)



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Injectable Solution
84,198mg/ml Imidocarb dipropionat

COMPOSITION

BABESIT Injectable Solution is a light yellow, clear, sterile injectable solution containing 120 mg of imidocarb dipropionate, equivalent to 84.198 mg of imidocarb per ml.

PHARMACOLOGICAL PROPERTIES

Pharmacodynamic properties:

Imidocarb is an antiprotozoan belonging to the carbanilides group, used in the treatment of Babesiosis. What is known about its mechanism of action is limited. In parasites, it affects the morphology of the cytoplasm and the number and size of the nucleus. The antiprotozoan effect is mediated by its action on the glycolysis of the parasite. After penetration into the parasite via urine-based protein carriers, it acts as an inhibitor of Type II topoisomerase. This effect blocks DNA replication and inhibits polyamine synthesis in the parasite.

Pharmacokinetic properties:

Pharmacokinetic studies have shown that imidocarb has long-lasting activity due to its binding to plasma and tissue proteins and its slow metabolism. In a radiolabeled study, administration of 3 mg/kg of imidocarb subcutaneously to lactating and non-lactating cows showed that half of the dose was excreted after 10 days.

It is primarily excreted in the feces. Plasma peak levels are reached 1 hour after administration (1.3 mg equivalent/kg). Peak levels in breast milk are reached 24 hours after administration (0.37 mg equivalent/kg) and are reduced to half level after 24 hours. It is mainly excreted as the parent compound. Imidocarb has been shown to cross the placental barrier.

USES / INDICATIONS

Cattle

Treatment and prevention of Babesiosis (*Babesia argentina*, *B. bigemina*, *B. bovis* and *B. divergens*.) and Anaplasma marginale,

Dog

Treatment and prevention of Babesiosis (*Babesia canis*, *B. gibsoni* and *B. vogelli*),

Horse

Treatment and prevention of Babesiosis (*B. equi* and *B. caballi*),

METHOD OF USE AND DOSAGE

Cattle

Babesiosis: Administered deep intramuscularly (hip or neck region) or subcutaneously.

Prevention: 2.125 mg imidocarb per kg body weight (2.5 ml per 100 kg body weight)

Treatment: 0.85 mg imidocarb per kg body weight (1 ml per 100 kg body weight)

A single injection is administered. Anaplasmosis: Bovine anaplasmosis: 2.125 mg imidocarb per kg body weight (2.5 ml per 100 kg body weight)

Dog:

Babesiosis: Administered intramuscularly or subcutaneously.

Protection: 4.25 mg imidocarb per kg body weight (0.5 ml per 10 kg body weight).

Protection does not exceed 4-6 weeks.

Treatment: 2.125 mg imidocarb per kg body weight (0.25 ml per 10 kg body weight)

A single injection is administered.

Horse:

Administered intramuscularly. For *B. caballi*, a single dose of 2 ml per 100 kg body weight is usually sufficient. However, for *B. equi*, two administrations at intervals of 24-72 hours may be necessary depending on the clinical condition of the disease. A single dose provides protection for up to 4 weeks. For sterilization of *B. caballi* infestations, 2 ml per 100 kg body weight should be applied twice at 24-hour intervals.

For sterilization of *B. equi* infestations, 4 ml per 100 kg body weight should be applied four times at 72-hour intervals.

In resistant cases in horses, there should be at least 6 weeks between subsequent sterilization applications.

SPECIAL CLINICAL INFORMATION AND WARNINGS FOR TARGET SPECIES

Imidocarb is an effective inhibitor of cholinesterase. The amount to be administered varies depending on the target species and purpose. In any case, high importance should be given to application according to live weight. For protection against babesiosis, it should be applied when symptoms are observed in one or two animals in the herd, or when cattle are transported to areas where *Babesia* is present.

All animals should be given a protective dose and kept under observation during the specified quarantine period.

The application provides a protective effect for up to 4 weeks, depending on the severity of exposure to the parasite. Immunity can be obtained if sufficient exposure to the parasite occurs during this period.

Body weight should be measured accurately and the recommended dose should not be exceeded.

Do not administer with other babecides. High dose administration may be painful and may cause animals to react. Some dogs may be hypersensitive to this pain.

Use during pregnancy and lactation:

No evidence of teratogenicity was found in studies conducted on laboratory animals.

The safety of this product in pregnant animals of the target species has not been studied. Therefore, it should be used according to the benefit/risk assessment of the veterinarian.

UNDESIRABLE/SIDE EFFECTS

General condition disorders (hyperthermia, sweating, fatigue), digestive system disorders (vomiting, colic, hypersalivation), neuromuscular disorders (tremor, convulsions) have been observed in target species. Salivation, restlessness, muscle tremors, tachycardia, cough, colic are rare. Deaths due to lactic shock have been observed after product application.

It is recommended that the veterinarian keep the treated animals under observation for 15 minutes after application. Cholinergic effects observed in animals after application may be corrected with atropine sulfate.

DRUG INTERACTIONS

Should not be mixed with other medicinal products.

Do not administer together with cholinesterase inhibitors.

OVERDOSE SYMPTOMS, PRECAUTIONS, ANTIDOTE

At 1.75 times the recommended dose, symptoms associated with anticholinergic activity begin to appear. Overdose can be treated with atropine sulfate. Death occurs at 5 times or more of the recommended dose.

RESIDUE WARNINGS IN FOOD-USE ANIMALS

Cattle should not be sent to slaughter for 213 days after administration, and cow's milk obtained for 21 days (42 milkings) from the last administration should not be offered for human consumption.

CONTRAINDICATIONS

Do not administer intravenously. Do not administer in repeated doses. Not to be used in animals known to be sensitive to the active or excipient substances. GENERAL WARNINGS

Read the leaflet before use. Consult a veterinarian before use and if any unexpected effects are observed. Keep out of reach of children and away from food.

PRECAUTIONS TO BE TAKEN BY THE USER AND WARNINGS FOR PHYSICIANS

Do not use or come into contact with this product if you have received medical advice that you should not work with products that exhibit anticholinesterase activity.

In case of contact with skin or eyes, rinse the area with plenty of water. Use appropriate protective measures when using the product. In case of accidental self-injection, seek immediate medical attention and show the product label and leaflet to your doctor.

If symptoms such as hypersalivation and muscular tremor, which indicate anticholinesterase activity, are observed, seek immediate medical treatment.

STORAGE CONDITIONS AND SHELF LIFE

It should be stored in its original packaging below 25°C without freezing or refrigeration.

Protect from sunlight. Shelf life is 24 months from the date of manufacture. After opening, store in its original packaging without freezing or refrigeration.

Shelf life is 28 days when stored below 25°C. Protect from sunlight.

The stopper should not be punctured more than 20 times after the first use.

WARNINGS FOR DISPOSAL AFTER USE AND FOR NON-TARGET SPECIES

Used or leftover product should be disposed of according to relevant legislation.

COMMERCIAL PRESENTATION

It is sold in 20 ml and 50 ml Type II amber colored glass bottles in a cardboard box, with a 20 mm grey bromobutyl stopper and a 20 mm blue ip-o cap.

PLACE AND CONDITIONS OF SALE

It is sold in pharmacies, veterinary clinics, polyclinics, and animal hospitals with a veterinary prescription (VHR).

PROSPECTUS APPROVAL DATE: 04.11.2022

**REPUBLIC OF TURKEY MINISTRY OF AGRICULTURE AND FORESTRY
MARKETING PERMIT DATE AND NUMBER:
04.11.2022-031/0004**

NAME AND ADDRESS OF MARKETING PERMIT HOLDER

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NAME AND ADDRESS OF MANUFACTURER

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