NOAH Compendium

MSD Animal Health UK Limited

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Imizol® 85 mg/ml Solution for Injection

Species: Cattle

Therapeutic indication:Pharmaceuticals: Endoparasiticides: Antiprotozoals

Active ingredient: Imidocarb Diproprionate

Product: Imizol® 85 mg/ml Solution for Injection

Product index: Imizol®

Cattle - milk:504 hours

Cattle - meat:213 days

Incorporating:

Qualitative and quantitative composition

Each ml contains:

Active substance:

Imidocarb 85.00 mg

(as Imidocarb dipropionate 121.15 mg)

For the full list of excipients, see section “Pharmaceutical particulars”.

Pharmaceutical form

Clear, colourless to pale brownish-yellow coloured solution.

Clinical particulars

Target Species:

Cattle

Indications for use:

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For the treatment and prevention of bovine babesiosis (Redwater fever - *Babesia divergens* infection) only.

Contraindications:

Do not administer the veterinary medicinal product by the intramuscular or intravenous route.

Do not administer repeat doses of the veterinary medicinal product.

Do not use in any other species.

Special warnings for each target species:

None.

Special precautions for use:

Estimate bodyweight carefully and do not exceed the recommended dosage.

Operator warnings:

Do not use if under medical advice not to work with compounds which may exhibit anti-cholinesterase activity.

Personal protective equipment (i.e., impermeable gloves) should be worn when handling the veterinary medicinal product.

Wash splashes of the veterinary medicinal product off the skin and eyes immediately.

In case adverse signs indicative of anti-cholinesterase activity are experienced by operators, seek medical advice immediately and show the package leaflet or the label to the physician.

Adverse Reactions:

Animals may show cholinergic signs after dosing. It may be possible to alleviate these side effects by treatment with atropine sulphate.

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Cholinergic disorder (e.g. Hypersalivation, Dis Cough, Colic)[1]; Anaphylaxis[2];

1symptoms can be alleviated by administering atropine sulphate.
2 may be fatal.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Use during pregnancy or lactation:

<u>Pregnancy:</u>

Treatment of pregnant animals has demonstrated that although the compound does cross the placental barrier there does not appear to be an adverse effect on the foetus or calf.

Interactions:

None known

Amounts to be administered and administration route:

Subcutaneous use.

The recommended dose regimen is as follows:

Indication	**Dose**
Therapy (Treatment)	1.0 ml/100 kg body weight (0.85 mg imidocarb/kg bw)
Prevention*	2.5 ml/100 kg body weight (2.125 mg imidocarb/kg bw)

* For therapy of in-contact animals known to be exposed to an infection.

To ensure a correct dosage, body weight should be determined as accurately as possible. The product should be administered on a single occasion only. Do not administer by the intramuscular or intravenous route. Do not inject more than 10 ml per injection site.

Overdose:

At about 1.75x overdose of the recommended dose signs consistent with cholinergic activity started to manifest themselves.

Death can result at doses of 5x the recommended therapeutic dose or greater.

Withdrawal periods:

Meat and offal: 213 days.

Milk: 21 days.

Pharmacological particulars

ATCvet code: QP51EX01

Pharmacological properties

Imidocarb dipropionate is a substituted carbanilide, used as an antiprotozoan treatment for the control of *Babesia* spp.

Little is known about the mode-of-action of imidocarb dipropionate. It appears that imidocarb acts directly on the parasite, causing alteration in number and size of nuclei and in morphology (vacuolation) of the cytoplasm. The antiprotozoan activity is derived from the carbanilide acting on glycolyis of the parasite. This is the result of this class of drugs giving rise to hypoglycaemia in the host. *Babesia* as well as many other parasites like trypanosomes depend upon host glucose for

aerobic glycolysis. There is also a selective blocking effect on the replication of the quinetoplastic DNA of the parasite.

Pharmacokinetics

Pharmacokinetic studies have been conducted with imidocarb dipropionate and have demonstrated that it has a long duration of activity, a result of it binding to plasma and tissue protein.

Imidocarb dipropionate is poorly absorbed when administered orally. Studies in rats, dogs and monkeys demonstrated that kidney and liver were the target organs, with it having the greatest affinity for kidney in rats and liver in the dog.

A radio-labelled study in lactating and non-lactating cattle, with imidocarb dipropionate being administered subcutaneously at a dose rate of 3 mg/kg body weight, demonstrated that imidocarb dipropionate was slowly excreted so that by 10 days post-dosing less than half the dose had been excreted. Main route of excretion was via the urine. Blood levels peaked at a mean level of 1.3 ppm equivalents 1 hour after injection. Milk levels peaked at a mean 0.37 ppm imidocarb dipropionate equivalents 24 hours post administration, and then depleted with a half-life of about 24 hours. All excreted material was mostly parent compound.

Other work has shown that imidocarb dipropionate can pass the placental barrier.

Studies have been conducted in sheep where imidocarb dipropionate was administered by intravenous injection at a dose rate of 2 mg/kg bodyweight. This was found to produce a peak level in plasma of 10.8 mg/ml, dropping to 1.9 mg/ml within an hour. It was also found that imidocarb dipropionate binds to plasma proteins, and detectable amounts were found in all major tissues up to four weeks after intramuscular injection.

Pharmaceutical particulars

Excipients:

Propionic acid (for pH adjustment)

Water for injections

Major incompatibilities:

None known.

Shelf-life:

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.

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

Special precautions for storage:

Do not store above 25 °C.

Do not freeze.

Protect from light.

This product does not contain an antimicrobial preservative. Avoid introduction of contamination.

Following withdrawal of the first dose, use the product within 28 days.

Immediate packaging:

100 ml amber glass (Type I) vial with blue rubber chlorobutyl bung with clear lacquered aluminium overseal.

OR

100 ml amber glass (Type I) vial with a grey laminated bromobutyl rubber stopper sealed with a flip-off seal comprising a silver aluminium collar covered with a green polypropylene cap.

Pack size

Cardboard box with 1 x 100 ml vial.

Disposal:

Medicines should not be disposed of via wastewater.

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.

Marketing Authorisation Holder (if different from distributor)

Intervet International B.V., represented by MSD Animal Health UK Limited.

Marketing Authorisation Number

UK: Vm 06376/4080

Significant changes

Date of the first authorisation or date of renewal

18 July 1990

Date of revision of the text

April 2025.

Any other information

When used for prevention, Imizol should be administered when clinical signs of the disease are observed in one or two cattle of a group or at the time of moving susceptible cattle into an area of known Babesia challenge. The entire group of animals should be dosed to provide protection against babesiosis, and all must be kept to the withhold times shown above. The product gives protection for

a period of up to 4 weeks depending on the severity of challenge. During this time, only if the challenge is adequate will immunity be established.

Veterinarians prescribing and/or treating animals that will enter the food chain with this product should notify the Animal and Plant Health Agency at Worcester APHA, County Hall, Spetchley Road, Worcester, WR5 2NP by email at this address CSCOneHealthVetMeds@apha.gov.uk with the name and address and CPH of the farmer on whose farm the product is to be administered and identity details of the animals treated. They should also inform the farmer that they must notify the APHA at the above address or on 03000 200 301 when treated animals are either to be slaughtered or their milk is to be used for human consumption.

For animal treatment only. Keep out of the sight and reach of children.

Legal category

Legal category:POM-V

GTIN

GTIN description:--

GTIN:--