1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imizol 85 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Imidocarb 85.00 mg
(as imidocarb dipropionate 121.15 mg)

Excipients:

Qualitative composition of excipients and other constituents
Propionic acid
Water for injection

A clear, colourless to brownish-yellow coloured solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

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

3.3 Contraindications

Do not administer intravenously or intramuscularly.
Do not administer repeat doses.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

When used for prevention, the veterinary medicinal product 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 should be dosed to provide protection against babesiosis, and all must be kept to the withhold times indicated.
The veterinary medicinal product gives protection for a period of up to four weeks depending on the severity of the challenge. During this time, only if the challenge is adequate will immunity be established.

Estimate body weight carefully and do not exceed the recommended dosage.

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

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

Wash splashes of the veterinary medicinal product off the skin and eyes immediately. Wear suitable protective clothing when using the veterinary medicinal product.

Seek medical advice immediately if adverse signs indicative of anti-cholinesterase activity are experienced by operators and show the package leaflet or the label to the physician. Adverse signs include hypersalivation and muscular tremor.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Rare (1 to 10 animals / 10,000 animals treated)	Hypersalivation, Colic; Discomfort; Muscle tremor; Tachycardia; Cough.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Cholinergic disorder[1]; Anaphylaxis[2].

[1] Symptoms can be alleviated by administering atropine sulfate.
[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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:

Imidocarb has been shown to be non-teratogenic in laboratory studies in rats and rabbits. 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.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer with cholinesterase inhibitors.

3.9 Administration routes and dosage

Subcutaneous use.

Dose rate:

Indication	**Dose**
Therapy (treatment)	1.0 ml/ 100 kg body weight
Prevention	2.0 ml/ 100 kg body weight

The veterinary medicinal product should be administered on a single occasion only. The rubber stopper should be limited to a maximum of ten piercings.

Do not administer by the intramuscular or intravenous route.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

At 1.75 x the recommended therapeutic dose, signs consistent with anti-cholinergic activity started to appear.
Overdose is treated with atropine sulphate.
Death can result at doses of 5 x the recommended therapeutic dose or greater.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Meat and offal: 213 days.
Milk: 21 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QP51EX01

4.2 Pharmacodynamics

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 glycolysis 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.

4.3 Pharmacokinetics

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

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 only half the dose had been excreted. Main route of excretion was via the faeces. Blood levels peaked at a mean level of 1.3 mg equivalents/kg 1 hour after injection. Milk levels peaked at a mean 0.37 mg equivalents/kg 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

100 ml multi-dose neutral amber glass Type 1 bottles sealed with a chlorobutyl rubber stopper and aluminium collar or a bromobutyl rubber stopper and flip-off aluminium seal with a polypropylene cap.

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

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10996/234/001

8. DATE OF FIRST AUTHORISATION

01/10/1999

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

27/09/2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).