# SUMMARY OF PRODUCT CHARACTERISTICS

## 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) |

**Excipient:**

| **Qualitative composition of excipients and other constituents** |
|---|
| Propionic acid (for pH adjustment) |
| Water for injections |

Clear, colourless to pale 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 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.

## 3.4 Special warnings

None

## 3.5 Special precautions for use

Special precautions for safe use in the target species:

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.
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.

Special precautions for the protection of the environment:

Not applicable.

## 3.6 Adverse events

Cattle:

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

[1] symptoms 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.

### 3.7 Use during pregnancy, lactation or lay

Pregnancy:
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

None known.

### 3.9 Administration routes and dosage

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 body weight) |
| Prevention* | 2.5 ml/100 kg body weight (2.125 mg imidocarb/kg body weight) |

* 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.

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

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.

### 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, 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 bodyweight, 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.

## 5. PHARMACEUTICAL PARTICULARS

### 5.1 Major incompatibilities

None known.

### 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.
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.

### 5.4 Nature and composition of 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.

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

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.

## 6. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

## 7. MARKETING AUTHORISATION NUMBER

Vm 06376/4080

## 8. DATE OF FIRST AUTHORISATION

18 July 1990

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

April 2025

## 10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

*Gavin Hall*

Approved 20 May 2025