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(s):	**mg**
Imidocarb	85.00
(as Imidocarb dipropionate	121.15)

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless to pale brownish-yellow coloured solution.

4. CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for Use:

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

4.3 Contra-indications:

* Imizol must not be administered intravenously or intramuscularly.
* Repeat doses of Imizol must not be given.

4.4 Special warnings for each target species

Not for use in any other species.

4.5 Special precautions for Use

Special precautions for use in animals

Estimate bodyweight 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 product off the skin and eyes immediately. Wear suitable protective clothing (i.e. impermeable gloves) when using the product.
Seek medical advice immediately if adverse signs indicative of anti-cholinesterase activity are experienced by operators.

4.6 Adverse reactions (frequency and seriousness)

Animals may show cholinergic signs after dosing. It may be possible to alleviate these side-effects by treatment with atropine sulphate.
While side-effects (salivation, discomfort, muscle tremors, tachycardia, cough, colics) are rare, they do occur and deaths from anaphylactoid reactions have been recorded following product use.

4.7 Use during pregnancy, lactation or lay

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.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

The product is for subcutaneous injection administration only. 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.

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.

4.10 Overdose (symptoms, emergency procedures, 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.

4.11 Withdrawal periods

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after a period of at least 213 days from treatment.
Milk for human consumption must not be taken during treatment. Milk must not be taken for human consumption from cattle until after at least 21 days from treatment.

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: QP51AE01

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 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propionic acid (for pH adjustment)
Water for injections

6.2 Major Incompatibilities

None known.

6.3 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.

6.4 Special Precautions for Storage

Do not store above 25°C. Protect from light. Do not freeze.
This product does not contain an antimicrobial preservative. Avoid introduction of contamination.
Following withdrawal of first dose, use the product within 28 days.

6.5 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.

6.6 Special Precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such product, if any

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor,Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4576

9. DATE OF FIRST AUTHORISATION

18 July 1990

10. DATE OF REVISION OF THE TEXT

September 2022

Approved 08 September 2022