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 mg
(equivalent to 121.1 mg imidocarb dipropionate)
For a full list of excipients see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection. A clear, pale amber coloured liquid.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do notadminister intravenously or intramuscularly.
Do not administer repeat doses.
Do not use in animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

When used for prevention, the 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 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 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 when using the product.

Seek medical advice immediately if adverse signs indicative of anti-cholinesterase activity are experienced by operators. Adverse signs include hypersalivation and muscular tremor.

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, colic) are rare, they do occur and deaths from anaphylactoid reactions have been recorded following product use.

4.7 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.

4.8 Interaction with other medicinal products and other forms of interactions

Do not administer with cholinesterase inhibitors.

4.9 Amounts to be administered and administration route

Route of administration: Subcutaneous injection only.
Dose rate:
Indication Dose
Therapy (treatment) 1.0 ml/ 100 kg body weight
Prevention 2.0 ml/ 100 kg body weight

The 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal period(s)

Meat and offal: 213 days.

Milk: 21 days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals, Carbanilides, imidocarb.
ATC vet code: QP51AE01.

5.1 Pharmacodynamic 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.

5.2 Pharmacokinetic particulars

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 ahalf-life of about 24 hours. All excreted material was mostly parent compound.

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propionic acid
Water for Injections

6.2 Major incompatibilities

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

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.

6.5 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.

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

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

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Limited
Magna Drive
Magna Business Park, Citywest Road
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10996/234/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 01 October 1999
Date of last renewal: 30 September 2009

10 DATE OF REVISION OF THE TEXT

December 2020