PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imizol 85 mg/ml Solution for Injection
Imidocarb

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Imidocarb	85 mg
(as imidocarb dipropionate	121.15 mg)

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route of administration: By subcutaneous injection. **Read the package leaflet before use.**

8. WITHDRAWAL PERIOD

Withdrawal Periods:

Meat and offal: 213 days

Milk: 21 days

9. SPECIAL WARNING(S), IF NECESSARY

Warnings:

Imizol must not be administered intravenously or intramuscularly.

Avoid introduction of contamination.

Repeat doses of Imizol must not be given to animals.

Operator warnings:

Do not use if under medical advice not to work with compounds which may exhibit anticholinesterase 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 anticholinesterase activity are experienced by operators.

Side Effects:

Animals may show cholinergic signs after dosing.

It may be possible to alleviate these side effects by treatment with atropine sulphate.

Deaths from anaphylactoid reactions have been recorded following product use.

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the container: 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not freeze.

Protect from light.

Keep the vial in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder
Intervet International BV
Wim de Korverstraat 35
5831 AN
Boxmeer
Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 06376/4080

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE THE IMMEDIATE PACKAGE
Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imizol 85 mg/ml Solution for Injection
Imidocarb

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Imidocarb	85 mg
(as imidocarb dipropionate	121.15 mg)

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Route of administration: By subcutaneous injection. **Read the package leaflet before use.**

8. WITHDRAWAL PERIOD

Withdrawal periods:

Meat and offal : 213 days

Milk: 21 days

9. SPECIAL WARNING(S), IF NECESSARY

Warnings:

Imizol must not be administered intravenously or intramuscularly.

Repeat doses of Imizol must not be given to animals.

Operator warnings:

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

See package leaflet for full user warnings.

Side Effects:

Read package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Shelf life after first opening the container: 28 days.

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not freeze.

Protect from light.

Keep the vial in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product or empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

[Distribution category]

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA holder
Intervet International BV
Wim de Korverstraat 35
5831 AN
Boxmeer
Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 06376/4080

17. MANUFACTURER’S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR:
Imizol 85 mg/ml Solution for Injection

FOR ANIMAL TREATMENT ONLY

Important Read before use

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Market authorisation holder:

Intervet International BV
Wim de Korverstraat 35
5831 AN
Boxmeer
Netherlands

Manufacturer responsible for batch release:

Vet Pharma Friesoythe GmbH
Sedelsberger Strasse 2-4
26169 Friesoythe
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imizol 85 mg/ml Solution for Injection
Imidocarb

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Each ml contains:

Imidocarb	85 mg
(as imidocarb dipropionate	121.15 mg)

A clear, colourless to pale brownish-yellow coloured aqueous solution for injection.

4. INDICATION(S)

For use in cattle only.

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

5. CONTRAINDICATIONS

Imizol must not be administered intravenously or intramuscularly.

Repeat doses of Imizol must not be given.

6. ADVERSE REACTIONS

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.

If you notice any side effects, even those not listed in this package leaflet or if you think this medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dose:

Cattle: For therapy, a single dose only of 1 ml Imizol Injection per 100 kg bodyweight.

For prevention, a single dose only of 2.5 ml Imizol Injection per 100 kg bodyweight.

Administration: Imizol must be administered subcutaneously, preferably in the neck.

9. ADVICE ON CORRECT ADMINISTRATION

Please refer to Section 8.

10. WITHDRAWAL PERIOD(S)

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 any 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 any treatment.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25°C.

Protect from light. Do not freeze.

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

Shelf life after first opening the container: 28 days.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

When the container is broached (opened) for the first time, the date on which any product remaining in the container should be discarded should be calculated. A statement of the in-use shelf-life of the product is given on this package insert. This discard date should be written on the space provided on the label.
Keep the vial in the outer carton.

12. SPECIAL WARNING(S)

Special precautions for use:

Estimate bodyweight carefully and do not exceed the recommended dosage.

Special warnings for each target species:

Not for use in any other species.

Use during 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.

Operator Warnings:

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.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

15. OTHER INFORMATION

For animal treatment only.

Further 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.

Pack size: Cardboard box with 1 x 100 ml vial.

Legal category: POM-V
To be supplied only on veterinary prescription.

Marketing authorisation number: Vm 06376/4080

Distributor in Northern Ireland:

Intervet Ireland Ltd.

Magna Drive, Magna Business Park

Citywest Road, Dublin 24, Ireland

Approved 28 June 2024

Gavin Hall