[Version 9, 03/2022] correc. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HEMOCARB 85 mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Imidocarb	85 mg
(as imidocarb dipropionate	121,15 mg)

Excipients:

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

Clear, pale yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and dogs.

3.2 Indications for use for each target species

Cattle:

- Treatment and prevention of piroplasmosis caused by *Babesia argentina*, *B. bigemina*, *B. bovis* and *B. divergens*.
- Treatment of anaplasmosis caused by *Anaplasma marginale*.

Dogs:

- Treatment of piroplasmosis caused by *Babesia canis*, *B. gibsoni* and *B. vogelli*.

3.3 Contraindications

Do not administer intravenously in cattle.
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

This veterinary medicinal product does not contain an antimicrobial preservative.

Special precautions for safe use in the target species:
Respect the doses. The weight of the animals should be determined as accurately as possible to avoid exceeding the recommended dose.

When this veterinary medicinal product is used for prevention of piroplasmosis in cattle it should be administered, to the entire group of animals, when clinical signs of the disease are observed in one or two cattle of a group or at the time of moving animals into an area affected for babesiosis. The product gives protection for a period of up to 4 weeks depending on the severity of challenge.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Symptoms of acetylcholinesterase inhibition include headache, blurred vision, hypersalivation, abdominal pain, mydriasis, muscle tremors, vomiting and diarrhea.
Do not use if under medical advice not to work with compounds which may exhibit anti-cholinesterase activity.
Administer the veterinary medicinal product with caution. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid contact with skin and eyes. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product. In case of spillage or accidental contact, wash immediately with plenty of water.
Do not eat, drink or smoke during use.
If you feel unwell after using this veterinary medicinal product, 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 and dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Cholinergic disorders*: • Vomiting, Stomach cramp, Hypersalivation, Diarrhoea • Tremor, Convulsion • Tachycardia, Cough, Excessive sweating, Prostration, Restlessness Injection site reaction Anaphylaxis (sometimes fatal)

*Cholinergic signs have been observed after administration of the veterinary medicinal product that can be alleviated by administering atropine sulphate.

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 also the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects.
The safety of the veterinary medicinal product has not been established during pregnancy.
Use only according to the benefit/risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer together with cholinesterase inhibitors.

3.9 Administration route and dosage

Cattle: Subcutaneous route.

- Piroplasmosis:
    - Prevention: administer 2 mg of imidocarb/kg b.w. (equivalent to 0,023 ml/kg b.w.) on a single occasion.
    - Treatment: administer 1 mg of imidocarb/kg b.w. (equivalent to 0,01 ml/kg b.w.) on a single occasion.
- Anaplasmosis treatment: administer 2,1 mg of imidocarb/kg b.w. (equivalent to 0,025 ml/kg b.w.) on a single occasion.

Do not inject more than 6 ml per injection site.

Dogs: Intramuscular or intravenous route.
Administer 4 to 5 mg of imidocarb/kg of body weight (equivalent to 0,047 – 0,058 ml/kg b.w.) on a single occasion.

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

In case of overdose, the symptoms described in section 3.6 may be aggravated. In this case, the recommended treatment is the administration of atropine sulphate.

3.11 Special restriction 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

3.12 Withdrawal periods

Cattle: Meat and offal: 213 days.
Milk: 6 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP51AE01

4.2 Pharmacodynamics

Imidocarb is an antiprotozoal derived from carbanilide. Its mechanism of action is little known. It seems to act directly on the glycolysis of the parasite and as an inhibitor of topoisomerase II, blocking DNA replication.
Its spectrum of action includes:

- Cattle: *Babesia argentina, B. bigemina, B. bovis, B. divergens, Anaplasma marginale*.
- Dogs: *Babesia canis, B. gibsoni, B. vogelli*.

4.3 Pharmacokinetics

Imidocarb dipropionate has a long duration of activity as a result of its slow metabolism and binding to plasma and tissue protein.

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: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3. Special precautions for storage

Do not store above 30ºC.
Keep the vial in the outer carton in order to protect from light and moisture.

5.4 Nature and composition of immediate packaging

Translucent polypropylene cylindrical vial closed with a type I bromobutyl rubber stopper and aluminum cap with Flip-Off® sealing.

Pack sizes:
Carton box with 1 vial of 10 ml.
Carton box with 1 vial of 20 ml.
Carton box with 1 vial of 50 ml.

Not all pack sizes may be marketed.

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

S.P. VETERINARIA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

ES: 3813 ESP
IT: 105277
PT: 317/01/19DFVPT
RO: 190211
BG: 0022-2932

EL: 154698/11-12-2019/K-0236901
CY: CY00757V
MT: VMA87

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD month YYYY}

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

DD/MM/YYYY

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

LABELLING FOR THE CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HEMOCARB 85 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Imidocarb ..... 85 mg
(as imidocarb dipropionate..... 121,15 mg)

3. PACKAGE SIZE

10 ml.
20 ml.
50 ml.

4. TARGET SPECIES

Cattle and dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

7. WITHDRAWAL PERIODS

Withdrawal period:
Cattle: Meat: 213 days.
Milk: 6 days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days.
Used by…

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 30ºC.

Keep the vial in the outer carton in order to protect from light and moisture.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

S.P. VETERINARIA, S. A.

14. MARKETING AUTHORISATION NUMBERS

ES: 3813 ESP
IT: 105277
PT: 317/01/19DFVPT
RO: 190211
BG: 0022-2932
EL: 154698/11-12-2019/K-0236901
CY: CY00757V
MT: VMA87

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABELLING FOR THE VIALS OF 10 ml, 20 ml and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HEMOCARB 85 mg/ml solution for injection

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE

Imidocarb 85 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 28 days.
Used by…

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

HEMOCARB 85 mg/ml solution for injection

2. Composition

Each ml contains:

Active substance:

Imidocarb	85 mg
(as imidocarb dipropionate	121,15 mg)

Clear, pale yellow solution.

3. Target species

Cattle and dogs.

4. Indications for use

Cattle:

- Treatment and prevention of piroplasmosis caused by *Babesia argentina*, *B. bigemina*, *B. bovis* and *B. divergens*.
- Treatment of anaplasmosis caused by *Anaplasma marginale*.

Dogs:

- Treatment of piroplasmosis caused by *Babesia canis*, *B. gibsoni* and *B. vogelli*.

5. Contraindications

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

6. Special warnings

This veterinary medicinal product does not contain an antimicrobial preservative.

Special warnings:

None.

Special precautions for safe use in the target species:

Respect the doses. The weight of the animals should be determined as accurately as possible to avoid exceeding the recommended dose.
When this veterinary medicinal product is used for prevention of piroplasmosis in cattle it should be administered, to the entire group of animals, when clinical signs of the disease are observed in one or two cattle of a group or at the time of moving animals into an area affected

for babesiosis. The product gives protection for a period of up to 4 weeks depending on the severity of challenge.

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

Symptoms of acetylcholinesterase inhibition include headache, blurred vision, hypersalivation, abdominal pain, mydriasis, muscle tremors, vomiting and diarrhea.
Do not use if under medical advice not to work with compounds which may exhibit anti-cholinesterase activity.
Administer the veterinary medicinal product with caution. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid contact with skin and eyes. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product. In case of spillage or accidental contact, wash immediately with plenty of water.
Do not eat, drink or smoke during use.
If you feel unwell after using this veterinary medicinal product, seek medical advice immediately and show the package leaflet or the label to the physician.

Pregnancy and lactation:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects.
The safety of the veterinary medicinal product has not been established during pregnancy.
Use only according to the benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

Do not administer together with cholinesterase inhibitors.

Overdose:

In case of overdose, the symptoms described in section "Adverse events" may be aggravated.
In this case, the recommended treatment is the administration of atropine sulphate.

<Special restrictions for use and special conditions for use:

Administration exclusively by a veterinarian surgeon (in case of intravenous administration) or under his supervision and control.>

Major Incompatibilities:

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

7. Adverse events

Cattle and dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Cholinergic disorders*: • Vomiting, Stomach cramp, Hypersalivation, Diarrhoea • Tremor, Convulsion

	• Tachycardia, Cough, Excessive sweating, Prostration, Restlessness Injection site reaction Anaphylaxis (sometimes fatal)

*Cholinergic signs have been observed after administration of the veterinary medicinal product that can be alleviated by administering atropine sulphate.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

8. Dosage for each species, routes and method of administration

Cattle: Subcutaneous route.

- Piroplasmosis:
  - Prevention: administer 2 mg of imidocarb/kg b.w. (equivalent to 0,023 ml/kg b.w.) on a single occasion.
  - Treatment: administer 1 mg of imidocarb/kg b.w. (equivalent to 0,01 ml/kg b.w.) on a single occasion.
- Anaplasmosis treatment: administer 2,1 mg of imidocarb/kg b.w. (equivalent to 0,025 ml/kg b.w.) on a single occasion.

Dogs: Intramuscular or intravenous route.
Administer 4 to 5 mg of imidocarb/kg of body weight (equivalent to 0,047 – 0,058 ml/kg b.w.) on a single occasion.

9. Advice on correct administration

Cattle: Do not inject more than 6 ml per injection site.

10. Withdrawal periods

Cattle: Meat: 213 days.
Milk: 6 days.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not store above 30ºC.
Keep the vial in the outer carton in order to protect from light and moisture.

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

Shelf life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

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 material derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorization numbers and pack sizes

ES: 3813 ESP
IT: 105277
PT: 317/01/19DFVPT
RO: 190211
BG: 0022-2932
EL: 154698/11-12-2019/K-0236901
CY: CY00757V
MT: VMA87

Pack sizes:
Carton box with 1 vial of 10 ml.
Carton box with 1 vial of 20 ml.
Carton box with 1 vial of 50 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

DD/MM/YYYY

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
S.P. VETERINARIA, S.A.
Ctra Reus Vinyols km 4.1
4330 Riudoms (Spain)

[ES:

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
S.P. VETERINARIA, S.A.
Ctra. Reus-Vinyols, km 4,1
43330 Riudoms (ESPAÑA)
Tel. +34 977 850 170
pharmacovigilance@spveterinaria.com]

Local representatives and contact details to report suspected adverse reactions:

<17. Other information>