[Version 8.1, 01/2017]

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:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear, pale yellow solution

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and dogs

4.2 Indications for use, specifying the 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*.

4.3 Contraindications

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

4.4 Special warnings for each target species

None

4.5 Special precautions for use

This veterinary medicinal product does not contain an antimicrobial preservative.

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

4.6 Adverse reactions (frequency and seriousness)

Cholinergic signs have been observed after administration of the veterinary medicinal product that can be alleviated by administering atropine sulphate.
Digestive: vomiting, cramping, hypersalivation and diarrhea.
Neuromuscular: tremors, convulsions and restlessness.
Other: tachycardia, cough, sweating and prostration.
A local reaction may occur at the injection site.
Deaths have been reported due to anaphylactic reactions after the use of the veterinary medicinal product.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Laboratory studies in rats and rabbits have no shown evidence of teratogenic effects.
The safety of the veterinary medicinal product has not been established during pregnancy.
Use only accordingly to the benefit/risk assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer together with cholinesterase inhibitors.

4.9 Amounts to be administered and administration route

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.

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.

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

In case of overdose, the symptoms described in section 4.6 may be aggravated. In this case, the recommended treatment is the administration of atropine sulphate.

4.11 Withdrawal periods

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals, carbanilides, imidocarb
ATCvet code: QP51AE01

5.1 Pharmacodynamic properties

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*.

5.2 Pharmacokinetic particulars

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

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

6.4. Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Translucent polypropylene cylindrical vial closed with a type I bromobutyl rubber stopper and aluminium 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.

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

SP VETERINARIA, SA
Ctra. Reus- Vinyols km 4.1
43330 RIUDOMS (Tarragona)

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: August 2019

10. DATE OF REVISION OF THE TEXT

DD/MM/YYYY

PROHIBITION OF SALE, SUPPLY AND/OR USE

Dispensing conditions: To be supplied only on veterinary prescription.
Administration conditions: Administration exclusively by a veterinarian surgeon (in case of intravenous administration) or under his supervision and control.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

LABELLING FOR THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HEMOCARB 85 mg/ml solution for injection
Imidocarb dipropionate

2. STATEMENT OF ACTIVE SUBSTANCE

Each ml contains:

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

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZES

10 ml
20 ml
50 ml.

5. TARGET SPECIES

Cattle and dogs

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

Read the package leaflet before use

8. WITHDRAWAL PERIODS

Cattle: Meat: 213 days
Milk: 6 days

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use

10. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days.

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of waste material in accordance with local requirements.

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

For animal treatment only. 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

S.P. VETERINARIA, S. A.
Crta. Reus - Vinyols Km 4,1
43330 Riudoms (Tarragona)

16. MARKETING AUTHORISATION NUMBER

17. MANUFACTURER'S BATCH NUMBER

Batch {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
Imidocarb dipropionate

2. QUANTITY OF THE ACTIVE SUBSTANCE

Imidocarb 85 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

Each ml contains:

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

4. ROUTES OF ADMINISTRATION

Dogs: Intramuscular or intravenous route
Cattle: Subcutaneous route

5. WITHDRAWAL PERIODS

Cattle: Meat: 213 days
Milk: 6 days

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once opened use within 28 days

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
HEMOCARB 85 mg/ml solution for injection

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

Marketing authorisation holder and manufacturer responsible for batch release:

S.P. VETERINARIA, S. A.
Crta. Reus - Vinyols Km 4,1
43330 Riudoms (Tarragona)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

HEMOCARB 85 mg/ml solution for injection
Imidocarb dipropionate

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substance:

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

Excipients, q.s.
Clear, pale yellow solution

4. INDICATIONS

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. ADVERSE REACTIONS

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

Digestive: vomiting, cramping, hypersalivation and diarrhea.

Neuromuscular: tremors, convulsions and restlessness.
Other: tachycardia, cough, sweating and prostration.
A local reaction may occur at the injection site.
Deaths have been reported due to anaphylactic reactions after the use of the veterinary medicinal product.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

Alternatively you can report via your national reporting system.

7. TARGET SPECIES

Cattle and dogs

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

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.

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.

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 container: 28 days.

12. SPECIAL WARNINGS

This veterinary medicinal product does not contain an antimicrobial preservative.

Special warnings for each target species:
None.

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

Pregnancy and lactation:
Laboratory studies in rats and rabbits have no shown evidence of teratogenic effects.
The safety of the veterinary medicinal product has not been established during pregnancy.
Use only accordingly 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 (symptoms, emergency procedures, antidotes):
In case of overdose, the symptoms described in section “Adverse reactions” may be aggravated.
In this case, the recommended treatment is the administration of atropine sulphate.

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

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD/MM/YYYY

15. OTHER INFORMATION

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