SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imidotyl 85 mg/ml solution for injection for cattle and dogs – BE, HR, EL, FR, HU, NL, RO
Imivet 85 mg/ml solution for injection for cattle and dogs - PL

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

Pale brownish-yellow coloured solution for injection free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, dogs.

3.2 Indications for use for each target species

Cattle:
- Treatment and prophylaxis of babesiosis caused by *Babesia divergens*, *B. bigemina* and *B. bovis.*
- Treatment of anaplasmosis caused by *Anaplasma marginale* and mixed infections by those *Babesia species* and *A. marginale.*
For prophylaxis, see also section "3.4. Special warnings".

Dogs:
- Treatment and prophylaxis of babesiosis caused by *Babesia canis* and *B. vogelli*.

3.3 Contraindications

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

3.4 Special warnings

In cattle prophylactic use is intended to overcome infections occurring in naïve animals exposed during the period of chemoprotection (up to 4 weeks), while allowing the subsequent development of an effective natural immunity.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Respect the doses and avoid combination with other babesicides. The administration of the highest doses can be painful and provoke defense reactions in animals. Some dogs are particularly sensitive to this pain.
Unnecessary use of the veterinary medicinal product or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy.
Use of the product should be based on identification of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product is an acetylcholinesterase inhibitor and may cause headache, blurred vision, hypersalivation, abdominal pain, mydriasis, muscle tremors, vomiting and diarrhea.
Avoid accidental self-injection and contact with skin and eyes including hand-to-mouth and hand-to-eye contact.
Administer medication with caution.
Do not eat, drink or smoke during use.
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.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
If you feel unwell after using this medicine, consult a doctor immediately and show him the package leaflet or the label.
This veterinary medicinal product may cause harm to the unborn child. Pregnant women should avoid exposure.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle, dogs:

Undetermined frequency (cannot be estimated from the available data)	Vomiting, abdominal cramp, hypersalivation, diarrhoea* Tremor, convulsions* Tachycardia, cough, hyperthermia* Increased sweating, prostration, restlessness* Injection site reaction Anaphylaxis**

* Colinergic signs have been observed after administration of the veterinary medicinal product and can be alleviated by administering atropine sulfate.
** Sometimes fatal

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 the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during pregnancy.

Pregnancy and lactation:

Studies in laboratory animals have not produced any evidence of teratogenic effects.
Use only accordingly 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 routes and dosage

For subcutaneous use in cattle.
For intramuscular or subcutaneous use in dogs.

In cattle:
For prophylaxis of babesiosis:
Single injection of 2.125 mg of imidocarb/kg bodyweight (equivalent to 2.5 ml of the product/100 kg bodyweight).
For treatment of babesiosis:
Single injection of 0.85 mg of imidocarb/kg bodyweight (equivalent to 1 ml of the product/100 kg bodyweight).
For treatment of anaplasmosis and mixed infections:
Single injection of 2,125 mg of imidocarb/kg bodyweight (equivalent to 2.5 ml of the product/100 kg bodyweight).

Do not inject more than 6 ml per injection site.

In dogs:
For treatment of babesiosis:
Administer 2.125 mg of imidocarb/kg of bodyweight (equivalent to 0.25ml of the product/10 kg bodyweight). Single injection is sufficient in most cases.

For prophylaxis of babesiosis:
Single injection of 4.25 mg of imidocarb/kg of bodyweight (equivalent to 0.5ml of the product/10 kg bodyweight). The duration of prevention will not exceed 4 to 6 weeks.

Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible.

The cap may be safely punctured up to 125 times.

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 restrictions 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

Antimicrobial medicinal products shall not be used for prophylaxis other than in exceptional cases, for the administration to an individual animal or a restricted number of animals when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP51EX01

4.2 Pharmacodynamics

Imidocarb is a carbanilide derivative with antiprotozoal activity. It has both babesicidal and anaplasmicidal properties. Its mechanism of action is little known. After active penetration into the parasite by purine base protein transporters, it could act as an inhibitor of topoisomerase II blocking DNA replication. It could also interfere with polyamine synthesis by the parasite.

4.3 Pharmacokinetics

According to European public MRL assessment report (EPMAR) calves were given a single subcutaneous dose of 3mg/kg bw ^{14}C-imidocarb dipropionate. Absorption of the dose was rapid with mean peak blood concentrations of 1316 µg equivalent/kg occurring 1 hour after dosing. More than 70% of the radioactivity was bound to plasma proteins. Most of the administered radioactivity was excreted in faeces (39% over 28 days) with smaller amounts in the urine (15%). Renal excretion was essentially complete in about 4 days whereas significant amount were excreted in faeces for up to 10 days after dosing. The major component of both urine and faeces was unmetabolized imidocarb.

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: 14 months
Shelf life after first opening the immediate packaging: 56 days

5.3 Special precautions for storage

Do not store above 25 °C.
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Colourless polypropylene vial closed with bromobutyl rubber stopper type I and aluminium cap with plastic lid.

Package sizes:
Cardboard box with 1 vial of 20 ml
Cardboard 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 product 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

Vet-Agro Multi-Trade Company Sp. z o.o.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

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).

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imidotyl 85 mg/ml solution for injection (RMS)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

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

3. PACKAGE SIZE

20ml
50ml

4. TARGET SPECIES

Cattle, dogs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle - subcutaneous use
Dogs- intramuscular or subcutaneous use

7. WITHDRAWAL PERIODS

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 56 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Keep the vial in the outer carton in order to protect from light.

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

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

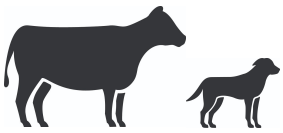
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imidotyl



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each ml contains:
Active substance:

Imidocarb	85 mg
(as imidocarb dipropionate	121.15 mg)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached use within 56 days.

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Imidotyl 85 mg/ml solution for injection for cattle and dogs (RMS)

2. Composition

Each ml contains:

Active substance:

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

Pale brownish-yellow coloured solution for injection free from visible particles.

3. Target species

Cattle, dogs.

4. Indications for use

Cattle:
- Treatment and prophylaxis of babesiosis caused by *Babesia divergens*, *B. bigemina* and *B. bovis*.
- Treatment of anaplasmosis caused by *Anaplasma marginale* and mixed infections by those *Babesia species* and *A. marginale.*

For prophylaxis, see also section "6. Special warnings".

Dogs:
- Treatment and prophylaxis of babesiosis caused by *Babesia canis* and *B. vogelli*.

5. Contraindications

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

6. Special warnings

Special warnings :
In cattle prophylactic use is intended to overcome infections occurring in naïve animals exposed during the period of chemoprotection (up to 4 weeks), while allowing the subsequent development of an effective natural immunity.

Special precautions for safe use in the target species:
Respect the doses and avoid combination with other babesicides. The administration of the highest doses can be painful and provoke defense reactions in animals. Some dogs are particularly sensitive to this pain.
Unnecessary use of the veterinary medicinal product or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy.
Use of the product should be based on identification of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product is an acetylcholinesterase inhibitor and may cause headache, blurred vision, hypersalivation, abdominal pain, mydriasis, muscle tremors, vomiting and diarrhea.
Avoid accidental self-injection and contact with skin and eyes including hand-to-mouth and hand-to-eye contact.
Administer medication with caution.
Do not eat, drink or smoke during use.
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.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
If you feel unwell after using this medicine, consult a doctor immediately and show him the package leaflet or the label.
This veterinary medicinal product may cause harm to the unborn child. Pregnant women should avoid exposure.

Special precautions for the protection of the environment:
Not applicable.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy.
Studies in laboratory animals have not produced any evidence of teratogenic effects.
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:
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:
Antimicrobial medicinal products shall not be used for prophylaxis other than in exceptional cases, for the administration to an individual animal or a restricted number of animals when the risk of an infection or of an infectious disease is very high and the consequences are likely to be severe.

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, dogs:

Undetermined frequency (cannot be estimated from the available data)	Vomiting, abdominal cramp, hypersalivation, diarrhoea* Tremor, convulsions* Tachycardia, cough, hyperthermia* Increased sweating, prostration, restlessness* Injection site reaction Anaphylaxis**

* Colinergic signs have been observed after administration of the veterinary medicinal product and can be alleviated by administering atropine sulfate.
** Sometimes fatal

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.

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

For subcutaneous use in cattle.
For intramuscular or subcutaneous use in dogs.

In cattle:
For prophylaxis of babesiosis:
Single injection of 2.125 mg of imidocarb/kg bodyweight (equivalent to 2.5 ml of the product/100 kg bodyweight).
For treatment of babesiosis:
Single injection of 0.85 mg of imidocarb/kg bodyweight (equivalent to 1 ml of the product/100 kg bodyweight).
For treatment of anaplasmosis and mixed infections:
Single injection of 2,125 mg of imidocarb/kg bodyweight (equivalent to 2.5 ml of the product/100 kg bodyweight).

Do not inject more than 6 ml per injection site.

In dogs:
For treatment of babesiosis:
Administer 2.125 mg of imidocarb/kg of bodyweight (equivalent to 0.25ml of the product/10 kg bodyweight). Single injection is sufficient in most cases.

For prophylaxis of babesiosis:
Single injection of 4.25 mg of imidocarb/kg of bodyweight (equivalent to 0.5ml of the product/10 kg bodyweight). The duration of prevention will not exceed 4 to 6 weeks.

9. Advice on correct administration

Underdosing could result in ineffective use and may favour resistance development.
To ensure a correct dosage, body weight should be determined as accurately as possible.
The cap may be safely punctured up to 125 times.

10. Withdrawal periods

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

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C.
Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 56 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 materials 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 authorisation numbers and pack sizes

Package sizes:
Cardboard box with 1 vial of 20 ml
Cardboard box with 1 vial of 50 ml
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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:
Vet-Agro Multi-Trade Company Sp. z o.o.
Gliniana 32
20-616 Lublin, Poland

Local representatives and contact details to report suspected adverse reactions:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information