1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Imidokal 85 mg/ml solution for injection for cattle and dogs

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 injection

Clear, pale brownish-yellow, free of visible particles solution

3. CLINICAL INFORMATION

3.1 Target species

Cattle, 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

Special precautions for safe use in the target species:
When used for prevention of piroplasmosis in cattle, the veterinary medicinal product should be administered to the entire group of animals when clinical signs of disease are observed in one or two cattle in the group, or at the time of moving susceptible cattle into an area of known *Babesia*

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

Unnecessary use of antiparasitics or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the product should be based on confirmation of the parasitic species and/or burden, or of the risk of infection based on its epidemiological features, for each individual animal/herd.

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 diarrhoea.
Avoid contact with skin and eyes. Do not use if under medical advice not to work with compounds which may exhibit anti-cholinesterase activity.
Administer medication with caution. Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product. Do not eat, drink or smoke during use.
In case of spillage or accidental contact, wash immediately with plenty of water.
If you feel unwell after using this medicine or in case of accidental self-injection, 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, dogs:

Undetermined frequency (cannot be estimated from the available data)	*Vomiting, abdominal cramp, hypersalivation, diarrhea *Tremor, convulsions *Tachycardia *Cough *Increased sweating *Prostration *Restlessness Injection site reaction Anaphylaxis (sometimes fatal)

*Cholinergic signs have been observed after administration of the product and can be alleviated by administering atropine sulfate.

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.

Use only according to the benefit-risk assessment by the responsible veterinarian.
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer with cholinesterase inhibitors.

3.9 Administration routes and dosage

Cattle- Subcutaneous use
Dogs- Intramuscular or intravenous use

Cattle:
For prevention of piroplasmosis:
Administer 2 mg of imidocarb/kg b.w. (equivalent to 0.023 ml/kg b.w.) on a single occasion.
For treatment of piroplasmosis:
Administer 1 mg of imidocarb/kg b.w. (equivalent to 0.01 ml/kg b.w.) on a single occasion.
For treatment of anaplasmosis:
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:
For treatment:
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.

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.
Accuracy of the dosing device should be thoroughly checked.
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 exacerbated. 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

Not applicable

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 an antiprotozoal derived from carbanilide. Little is known about its mechanism of action. It seems to act directly on glycolysis of the parasite and as an inhibitor of topoisomerase II, blocking DNA replication.

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

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Colourless polypropylene plastic bottle 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 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

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

7. MARKETING AUTHORISATION NUMBER(S)

VPA20742/009/001

8. DATE OF FIRST AUTHORISATION

29 September 2023

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).