PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:

Imidocarb	85 mg
(as imidocarb dipropionate	121.15 mg)

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

3. Target species

Cattle, 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

Special warnings :
None.

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.

Pregnancy and lactation:
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.

Interaction with other medicinal products and other forms of interaction:
Do not administer 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.

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, 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 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 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.

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.

9. Advice on correct administration

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

10. 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 containing 1 vial of 20 ml.
Cardboard box containing 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

{logo of the marketing autorisathion holder}