IMICARE INJECTION

(Imidocarb Dipropionate)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

IMICARE INJECTION.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Imidocarb Dipropionate.....120mg

3. PHARMACEUTICAL FORM

Solution for Injection.

4. CLINICAL INFORMATION

4.1. Target species

Cattle & Dogs

4.2. Indications for use specifying the target species

Cattle:

- Treatment and prophylaxis of babesiosis, anaplasmosis and mixed infections.

Dogs:

- Treatment and prophylaxis of babesiosis.

4.3. Contraindications

None.

4.4. Special warnings for each target species

Imidocarb is a potent cholinesterase inhibitor. Dosage varies depending on the species and intended purpose. In all cases, it must be strictly adjusted to the animal's weight.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Do not administer intravenously.

Strictly respect the indicated doses and avoid combination with other babesicides. Administration of higher doses can be painful and cause defensive reactions in animals. Some dogs are particularly sensitive to this pain.

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

None.

4.6. Adverse reactions (frequency and seriousness)

Dogs:

Very rare (<1 animal / 10,000 animals treated, including isolated	Digestive disorders (e.g. Vomiting, Colic, Hypersalivation);
reports):	Neuromuscular disorders (eg. Tremors, Seizures); Hyperthermia, prostration; Sweating

Cattles:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive disorders (e.g. Vomiting, Colic, Hypersalivation); Neuromuscular disorders (eg. Tremors, Seizures); Hyperthermia, prostration;
Frequency undetermined (cannot be estimated from the available data):	Sweating

It is important to report adverse reactions. Reporting allows for continuous monitoring of the safety of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, either to the marketing authorization holder or to the national competent authority via the national reporting system. See also the "Contact details" section of the package leaflet."

4.7. Use during pregnancy and lactation or lay

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

Gestation:

Use in pregnant females should only be carried out after an assessment of the benefit/risk ratio established by the responsible veterinarian.

Studies in laboratory animals have not shown any teratogenic effects.

4.8. Interaction with other veterinary medicinal products and other forms of interaction

None known.

4.9. Dosage and administration route

Intramuscular or subcutaneous routes.

1. Treatment of babesia

(B.divergens, B.bovis, B.bigemina, B.equi, B.caballi, B.ovis, B.canis)

• Cattle & Sheep: 1ml/100kg bwt

• Horses, donkeys & mules:

2ml/100kg bwt

2. Treatment of anaplasmosis and mixed infection due to Anaplasma & Babesia

o Cattle:

2.5ml/100 kg bwt

3. Prophylaxis of babesiosis in cattle and horses

o Cattle:

2.5ml/100 kg bwt

A single dose will prevent babesiosis for up to 4 weeks depending on the severity of the challenge and species

Equines:

2ml/100 kg bwt

A single dose will prevent babesiosis for up to 4 weeks

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

See "Adverse effects" section

4.11. Restrictions and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary drugs, in order to reduce the risk of resistance development

Medication administered under the control or supervision of the veterinarian

4.12. Withdrawal period:

Cattle:

Meat and offal: 28 days

Milk: 3 days.

For Dogs: Not applicable

5. PHARMACOLOGICAL PROPERTIES

ATCVet Code: **QP51EX01**.

5.1. Pharmacodynamics properties

Imidocarb, a carbanilide derivative, has both babesicidal and anaplasmicidal properties. Its mechanism of action is poorly understood. After active penetration into the parasite via purine base protein transporters, it may act as a type II topoisomerase inhibitor. It thus blocks DNA replication; it may also interfere with polyamine synthesis by the parasite.

5.2. Pharmacokinetic information

Following intramuscular or subcutaneous administration in animals, imidocarb is absorbed and widely distributed, binding significantly to plasma and tissue proteins, resulting in a long duration of action. It undergoes slow elimination, primarily through renal excretion of the unchanged drug. Hepatic metabolism appears to be minimal. The prolonged presence in tissues can lead to a reservoir effect.

6. PHARMACEUTICAL INFORMATION

6.1. List of excipients

Propionic acid
Water for Injection

6.2. Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product should 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 container: use immediately in 28 days, do not store.

6.4. Special precautions for storage

Store below 25°C.

Protect from light and moisture.

Keep out of the reach of children.

To be used as directed by the registered veterinary practitioner only.

6.4. Nature and composition of primary conditioning

Cardboard box with glass injection vial (s).

Glass vial is closed with a bromobutyl rubber stopper and sealed with an aluminum flip off seal.

Pack sizes: 100ml

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Any unused veterinary medicinal products or waste materials derived from such medicinal products should be disposed of in accordance with local requirements and placed in appropriate collection and disposal systems for unused or expired medicinal products.

7. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd.

Plots No. 136-138, Sector-15,

Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No: 128441

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 30th July 2025

10. DATE OF REVISION OF THE TEXT

01-08-2025

MANUFACTURED BY:

