HEPAWAN INJECTION

(Phenoxy-2-Methyl-2-Propionic Acid)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

HEPAWAN INJECTION.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:

Phenoxy-2-Methyl-2-Propionic Acid...... 100mg

3. PHARMACEUTICAL FORM

Solution for Injection.

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Horses, Goats & Dogs.

4.2. Indications for use specifying the target species

For those processes in which liver dysfunction or alteration is involved. In particular:

Cattle, goats: ketosis (acetonemia) - dyspepsia with bloating - ruminal impaction - food toxicosis - complementary treatment in cases of distomatosis and dicroceliosis.

Horses: liver disorders due to nutritional imbalance - liver failure due to piroplasmosis and leptospirosis.

Dogs: jaundice - liver failure - as an adjuvant during the treatment of leptospirosis and distemper.

4.3. Contraindications

None.

4.4. Special warnings for each target species

Not Reported

4.5. Special precautions for use

Special precautions for safe use in the target species:

Not applicable.

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

Do not smoke or eat while handling the veterinary medicinal product.

Wash hands after use. Read the package insert before use.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. Any symptoms should be treated symptomatically.

4.6. Adverse reactions (frequency and seriousness)

No adverse effects are known at the prescribed doses, nor have they been reported after administration at higher doses.

4.7. Use during pregnancy and lactation or lay

It can be used during pregnancy and lactation.

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

No data available.

4.9. Dosage and administration route

Deep intramuscular, intraperitoneal or slow intravenous route.

For all target species the dosage is 10 mg of phenoxy-2-methyl-2-propionic acid (sodium salt) per kg of body weight (equivalent to 1 ml of medicine/10 kg bw).

Adult cattle and horses: Up to 300 kg body weight: 30 ml

Up to 500 kg body weight: 40 ml Over500 kg body weight: 50 ml

Calves, foals, goats, 5-15 ml

Dogs: 1 ml of veterinary medicine/10 kg body weight

Inject by deep intramuscular route, intraperitoneal or intravenously (slowly).

The above doses may be repeated every 24 hours at the discretion of the veterinarian.

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

Not Known.

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:

Meat (beef & goat): zero days.

Milk (bovine & caprine): zero hours.

Horse: Not Applicable.

5. PHARMACOLOGICAL PROPERTIES

ATCVet Code: QA05BA

5.1. Pharmacodynamics properties

This veterinary medicine is an aqueous solution containing 10% phenoxy-2-methyl-2-propionic acid, which is characterized by its selective action on the liver, increasing bile secretion and thus promoting digestive functions.

This action of stimulating secretion is carried out by acting directly on the glandular system, without exciting or depressing the central or autonomic nervous systems.

Due to this choleretic action, it is indicated in the treatment of all disorders characterized by liver failure or associated with it.

5.2. Pharmacokinetic information

Administered parenterally, it is rapidly absorbed and eliminated in urine and feces in an unchanged form in cows

6. PHARMACEUTICAL INFORMATION

6.1 List of Excipients

Methyl parahydroxybenzoate, sodium salt (E219) Propyl parahydroxybenzoate, sodium salt Water for injections

6.2 Incompatibilities

This veterinary medicinal product is not miscible with calcium salts.

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 within 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.

6.5. Nature and composition of primary conditioning

Cardboard box with glass vial injection.

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

Pack sizes: 50ml

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.: 089828

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 11-05-2018

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:

