ACLOWAN INJECTION
(Aceclofenac)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

ACLOWAN INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:
Aceclofenac …….. 25mg

3. PHARMACEUTICAL FORM

Solution for Injection

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Sheep, Goat, Dog, Buffaloes, Camel, Horse.

4.2. Indications for use specifying the target species

For the treatment of inflammation, pain, and pyrexia associated with:
Musculoskeletal disorders
Mastitis
Respiratory infections
Post-surgical recovery

4.3. Contraindications

Do not use in animals with known hypersensitivity to NSAIDs.
Contraindicated in animals with gastrointestinal ulceration, hepatic or renal impairment, or bleeding disorders.
Do not use in dehydrated, hypovolemic or hypotensive animals.

4.4. Special warnings for each target species

Use with caution in animals under stress or concurrent illness.
Adequate hydration and monitoring are advised when used alongside nephrotoxic drugs.

4.5. Special precautions for use

Special precautions for safe use in the target species:

Avoid repeated injections at the same site. Use strict aseptic technique.

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

People with known hypersensitivity to the active substances should avoid contact with the veterinary medicinal product.
Avoid contact with eyes, skin, and mucous membranes.
Wash hands thoroughly after handling the product.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label.

4.6. Adverse reactions (frequency and seriousness)

Mild local swelling may occur at the injection site.
Rare cases of gastrointestinal irritation or renal stress.
Hypersensitivity reactions may occur in predisposed animals.

4.7. Use during pregnancy and lactation or lay

Not recommended.

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

Do not use with other NSAIDs or corticosteroids.
Use cautiously with nephrotoxic drugs or anticoagulants.

4.9. Dosage and administration route

Route: Intramuscular injection (IM)
Dosage:

- **Cattle, buffalo, horse**: 1 mL/20 kg body weight (1.25 mg/kg) once daily
- **Dogs**: 0.5–1 mL/10 kg body weight (1.25–2.5 mg/kg)
- **Sheep/goats**: Use with caution, same dose as cattle
- **Duration:** Usually 1–3 days depending on clinical response

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

May cause GI ulceration, renal or hepatic stress. No specific antidote. Treat symptomatically.

4.11. Special restrictions on use and special conditions of 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.

4.12. Withdrawal Period:

Meat and offal: 7 days
Milk**:** 3 days
Dog & Horse: Not Applicable

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Non-steroidal anti-inflammatory drug (NSAID), acetic acid derivative.

5.1. Pharmacodynamics properties

Aceclofenac is a non-steroidal anti-inflammatory drug (NSAID) that selectively inhibits cyclooxygenase-2 (COX-2) more than COX-1.
It reduces the synthesis of prostaglandins, thus exhibiting anti-inflammatory, analgesic, and antipyretic effects.

5.2 Pharmacokinetic information

After intramuscular or intravenous injection, Aceclofenac is rapidly absorbed, reaching peak plasma concentrations in about 1–2 hours.
It is highly protein-bound (~99%), extensively metabolized in the liver (mainly to 4′-hydroxyaceclofenac), and excreted via urine.
The elimination half-life is approximately 4–5 hours.

6. PHARMACEUTICAL INFORMATION

6.1 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.2. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the container: use immediately, do not store.

6.2. Special precautions for storage

Store below 30°C & in a dry place.
Protect from light & moisture.
Keep out of the reach of children.
To be used as directed by the registered veterinary practitioner only.

6.3. Nature and composition of primary conditioning

The product is available in packages of 50 ml in amber glass vial. The vials are closed with bromobutyl rubber stoppers and sealed with aluminum flip off seal.

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

Waste materials derived from the use of such products
Medicinal products should not be disposed of via wastewater or household waste.
Use return systems for unused veterinary medicinal products or waste materials derived from such products, in accordance with local requirements and national collection systems applicable to the veterinary medicinal product concerned.
Treated animals should be kept in shelters throughout the treatment period and their droppings should be collected and NOT used for soil fertilization.

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.: 091887

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 19-09-2018

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD.
136, Sector 15, Korangi Industrial Area, Karachi-74900, Pakistan.