KETOWAN INJECTION
(Ketoprofen)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

KETOWAN INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:
Ketoprofen 100mg

3. PHARMACEUTICAL FORM

Solution for Injection.

4. CLINICAL INFORMATION

4.1. Target species

Cattle and Horses

4.2. Indications for use specifying the target species

Bovine:
Anti-inflammatory, analgesic and antipyretic treatment in cases of: inflammatory processes associated with respiratory diseases, breast edema, acute mastitis, musculoskeletal inflammatory processes.

Horses:
Treatment of inflammatory and painful conditions of the osteoarticular and musculoskeletal systems, in particular: lameness of traumatic origin, arthritis, arthrosis, joint trauma (sprains, synovitis), fractures, tendonitis, foot conditions (navicular disease, horseshoe accidents, pododermatitis circumscripta, infosura), post-surgical inflammation.
Symptomatic treatment of colic.

4.3. Contraindications

Do not use in cases of severe renal failure.
Do not use in cases of hypersensitivity to the active ingredient or any of the excipients.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

Special precautions for use in animals
Do not use in foals less than 15 days old.
Special precautions to be taken by the person administering the product to animals:
Hypersensitivity (allergy) reactions may occur. People with known hypersensitivity to ketoprofen and/or benzyl alcohol should avoid contact with the veterinary medicinal product.

Administer the veterinary medicinal product with caution. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. The veterinary medicinal product may cause irritation after contact with skin or eyes. Avoid contact with skin and eyes. In case of accidental contact, wash immediately with plenty of water.
If irritation persists, consult a doctor and show him/her the leaflet or label.
Wash your hands after using the medication.

Special precautions for the protection of the environment:

Not true

4.6. Adverse reactions (frequency and seriousness)

Cattle and horses

Frequency not known (cannot be estimated from the available data)	Edema at the administration site1 Pain at the injection site1 Inflammation at the injection site1

1 Affectation within a 10 cm radius that disappears one week after finishing treatment.

Reporting adverse events is important. It allows for continued monitoring of the safety of a veterinary medicinal product. Notifications should preferably be sent via a veterinarian to the marketing authorisation holder or to the national competent authority via the national notification system.

4.7. Use during pregnancy and lactation or lay

Safety studies of ketoprofen carried out in laboratory animals (rats, mice and rabbits) and in cattle have not demonstrated teratogenic or toxic effects on the fetus.

The safety of ketoprofen on fertility, pregnancy or fetal health in horses has not been demonstrated.

Gestation:
It can be used in cows during gestation.
Do not use this medicine in mares during pregnancy.

Lactation:
It can be used in cows during lactation.

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

Do not administer in conjunction with other non-steroidal anti-inflammatory drugs, diuretics or anticoagulants.

4.9. Dosage and administration route

Bovine: intravenous or intramuscular route
Administer 3 mg of ketoprofen/kg of body weight (Equivalent to 3 ml/100 kg of body weight) per day for 1 to 3 consecutive days.

Horses: intravenous route
For the treatment of musculoskeletal and osteoarticular system conditions, administer 2.2 mg of ketoprofen/kg bw (Equivalent to 1 ml/45 kg bw) per day for 3 to 5 consecutive days.

For symptomatic treatment of colic, administer 2.2 mg ketoprofen/kg bw (equivalent to 1 ml/45 kg bw) in a single injection. Generally, a single injection is sufficient; any additional injection should be preceded by a clinical re-evaluation of the animal.
Animal weights should be determined as accurately as possible to ensure correct dosing.

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

The following can be identified: anorexia, vomiting and diarrhea.

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

Administration exclusively by the veterinarian (in the case of intravenous administration) or under his supervision and control.

4.12. Withdrawal period:

Bovines: Meat: 4 days.
Milk: Zero hours.
Use is not authorized in Bovines whose milk is used for human consumption.

Hourse:
Not applicable

5. PHARMACOLOGICAL PROPERTIES

ATCvet code: **QM01AE03**

5.1. Pharmacodynamic properties

Ketoprofen is a non-steroidal anti-inflammatory drug with analgesic properties, belonging to the propionic acid group.
Inflammatory stimuli that damage cells activate phospholipases, which release arachidonic acid. This is the substrate of the cyclooxygenase and lipoxygenase enzyme systems, whose activity results in the production of important mediators of inflammation: prostaglandins, thromboxane and leukotrienes. Ketoprofen acts as a double inhibitor of inflammation, inhibiting both the cyclooxygenase and lipoxygenase pathways and thus preventing the production of prostaglandins and leukotrienes.

Ketoprofen is also a powerful analgesic with central and peripheral effects. Its action consists of directly inhibiting bradykinin, a vasodilator and pain mediator. Bradykinin initiates the painful impulse by exciting the nerve endings of the nociceptors.
In addition to its anti-bradykinin activity, ketoprofen acts at the level of the central nervous system to inhibit the perception of pain.

Furthermore, ketoprofen counteracts the effect of endotoxins in horses and antagonizes intestinal spasm induced by bradykinin.

5.2. Pharmacokinetic information

Ketoprofen is rapidly absorbed. In cattle, the maximum plasma concentration (8.025 ± 1.9 ÿg/ml) is reached in less than one hour after intramuscular administration and bioavailability is almost complete. It is highly bound to plasma proteins (greater than 98%) and is concentrated in inflamed tissues. It also has a strong affinity for synovial tissue. It is rapidly distributed and eliminated quickly.

The duration of action is longer than would be expected from its half-life, which varies between less than one hour (in equines by IV route) and more than five hours (in cattle after IM administration). Ketoprofen passes into the synovial fluid and remains there at higher levels than in plasma, with a half-life two to three times longer than in plasma. Ketoprofen is metabolized in the liver, giving rise to metabolites without significant biological activity, with 90 percent being excreted in the urine in the form of metabolites conjugated with glucuronic acid.

6. PHARMACEUTICAL INFORMATION

6.1 List of excipients

Benzyl Alcohol
Arginine
Citric acid monohydrate
Water for injection

Incompatibilities

Do not mix with acidic substances.
Do not mix with any other veterinary medicine in the same syringe.

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 within 7 Days

6.3. 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).
Vial is closed with a bromobutyl rubber stopper and sealed with an aluminum flip off seal.
Pack sizes: 50ml

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.: 088079

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 23-02-2018

10. DATE OF REVISION OF THE TEXT

17-02-2025

MANUFACTURED BY:

NAWAN LABORATORIES (PVT) LTD.
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