AXCEN INJECTION
(Flunixin)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

AXCEN INJECTION

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml Contains:
Flunixin (as Meglumine) …….. 50mg

3. PHARMACEUTICAL FORM

Solution for Injection.

4. CLINICAL INFORMATION

4.1. Target species

Cattle & Horses

4.2. Indications for use specifying the target species

In horses:
- Alleviation of inflammation and pain associated with musculoskeletal disorders.
- Alleviation of visceral pain associated with colic.
- Adjunctive therapy in the treatment of endotoxaemia and septic shock.

In cattle:
- Reduction of acute inflammation associated with respiratory disease.
- Adjunctive therapy in the treatment of acute mastitis.

4.3. Contraindications

Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastrointestinal ulceration or bleeding, where there is evidence of a blood dyscrasia.
Do not use in case of hypersensitivity to flunixin meglumine, other NSAIDs or any of the excipients.
Do not use in case of haemorrhagic disorders.
Do not use in animals suffering from chronic musculo-skeletal disorders.
Do not administer to pregnant sows, gilts at mating and in breeding boars.
Do not use the product within 48 hours before expected parturition in cows.

4.4. Special warnings for each target species

The cause of the underlying inflammatory condition should be determined and treated with appropriate concomitant therapy.

4.5. Special precautions for use

Special precautions for use in animals:

Avoid intra-arterial injection.

Use in any animal less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided animals may require a reduced dosage and careful clinical-management.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal except in the case of endotoxaemia or septic shock.
It is preferable that NSAIDs, which inhibit prostaglandin synthesis are not administered to animals undergoing general anaesthesia until fully recovered.
NSAIDS are known to have the potential to delay parturition through a tocolytic effect by inhibiting prostaglandins that are important in signalling the initiation of parturition. The use of the product in the immediate post- partum period may interfere with uterine involution and expulsion of foetal membranes resulting in retained placentae.
Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

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.
Keep out of reach of children.
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)

Flunixin meglumine is a non-steroidal anti-inflammatory drug (NSAID). Untoward effects include gastrointestinal irritation,ulceration, hepatic idiosyncratic reactions, and, especially in dehydrated or hypovolaemic animals, potential for renal damage.

4.7. Use during pregnancy and lactation or lay

May be used in pregnant and lactating cattle.
For pregnant mares, use only according to the benefit/risk assessment by the Responsible Veterinarian.
Do not administer to pregnant sows, gilts at mating and in breeding boars.
The product should only be administered within the first 36 hours post-partum following a benefit/risk assessment performed by the responsible veterinarian and treated animals should be monitored for retained placentae.

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

Monitor drug compatibility closely where adjunctive therapy is required. Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other, as it may increase the toxicity, mainly gastro-intestinal, even with low doses of acetylsalicylic acid. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.

The concurrent administration of corticoids may increase toxicity of the two products and increase the risk of gastro-intestinal ulceration. It should therefore be avoided.
Flunixin may reduce the effect of some anti-hypertensive medicinal product by inhibition of the prostaglandins synthesis, such as diuretics, Angiotensin Conversion Enzyme (ACE) inhibitors and beta blockers. Concurrent administration of potentially nephrotoxic drugs, particularly aminoglycosides,should be avoided.
Flunixin may reduce renal elimination of some drugs and increase their toxicity (for example, aminoglycosides).

4.9. Dosage and administration route

For intravenous administration to cattle and horses.

HORSES:
For use in equine colic, the recommended dose rate is 1.1 mg flunixin/kg bodyweight equivalent to 1 ml per 45 kg bodyweight. Treatment may be repeated once or twice if colic recurs.

For use in musculo-skeletal disorders, the recommended dose rate is 1.1 mg flunixin/kg bodyweight equivalent to 1 ml per 45 kg bodyweight, once daily for up to 5 days according to clinical response.

For the treatment of endotoxaemia or septic shock associated with gastric torsion and with otherconditions in which the circulation of blood to the gastrointestinal tract is compromised: 0.25 mg/kg (1 ml per 200 kg) every 6-8 hours.

CATTLE
The recommended dose rate is 2.2 mg flunixin/kg bodyweight equivalent to 2 ml per 45 kg bodyweight. Repeat as necessary at 24 hour intervals for up to 5 consecutive days.

An appropriate graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.
The stopper should not be punctured more than 50 times. A draw-off needle should be used to avoid excessive puncturing of the stopper.
Do not exceed the stated dose or duration of treatment.

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

Over dosage is associated with gastrointestinal toxicity.

4.11. With drawl period:

Cattle:
Meat and offal: 10 Days
Milk: 24 Hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-Inflammatory and antirheumatic products, non-steroids – Fenamates
ATCvet code: **QM01AG90**

5.1. Pharmacodynamics properties

Flunixin meglumine is a relatively potent non-narcotic, non-steroidal analgesic with anti-inflammatory, anti-endotoxic and anti-pyretic properties.

Flunixin meglumine acts as a reversible inhibitor of cyclo-oxygenase, an important enzyme in the arachidonic acid cascade pathway which is responsible for converting arachidonic acid to cyclic endoperoxides. Consequently, synthesis of eicosanoids, important mediators of the inflammatory process involved in central pyresis, pain perception and tissue inflammation, is inhibited. Through its effects on the arachidonic acid cascade, flunixin also inhibits the production of thromboxane, a potent platelet pro-aggregator and vasoconstrictor which is released during blood clotting. Flunixin exerts its antipyretic effect by inhibiting prostaglandin E2 synthesis in the hypothalamus. By inhibiting the arachidonic acid cascade pathway, flunixin also produces an anti-endotoxic effect by suppressing eicosanoid formation and therefore preventing their involvement in endotoxin associated disease states.

5.2 Pharmacokinetic information

Flunixin was administered intravenously to horses as a single dose of 1.1 mg/kg. At the first timepoint measured (10 minutes after administration) the plasma concentration was 11.45 µg/ml, AUC was 21.45 µg.h/ml and the elimination half-life was approximately 2 hours.
Flunixin was administered intravenously to cattle as a single dose of 2.2 mg/kg. At the first timepoint measured (10 minutes after administration) the plasma concentration was 12.32 µg/ml, AUC was 14.87 µg.h/ml and the elimination half-life was approximately 4 hours.

Environmental properties:

Flunixin is toxic to avian scavengers although foreseen low exposure leads to low risk.

6. PHARMACEUTICAL INFORMATION

6.1 Incompatibilities

In the absence of incompatibility studies, this medicinal product must not be mixed with other 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 within 28 days do not store.

6.3. Special precautions for storage

Store below 25 °C.
Protect from light.
Keep out of reach and sight of children
Discard unused product.
To be used as directed by the registered veterinary practitioner only.

6.4. Nature and composition of primary conditioning

50ml amber glass vial, closed with a bromobutyl rubber stopper and capped with an aluminium flip off seal.

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.: 081320

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 15-08-2016

10. DATE OF REVISION OF THE TEXT

05-01-2025

MANUFACTURED BY:

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