SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flunixin 50 mg/ml Solution for Injection for Cattle, Horses and Pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Flunixin (as flunixin meglumine)	50 mg

Excipients:

Phenol	5.0 mg
Sodium Formaldehyde Sulphoxylate Dihydrate	2.5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
A clear colourless solution

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, Horses and Pigs

4.2 Indications for use, specifying the target species

In horses, indicated for the alleviation of inflammation and pain associated with musculo-skeletal disorders and for the alleviation of visceral pain associated with colic, also indicated for the treatment of endotoxaemia or septic shock associated with gastric torsion and for other conditions in which the circulation of the blood to the gastrointestinal tract is compromised.

In cattle, indicated for the control of acute inflammation associated with respiratory disease. It may also be used as adjunctive therapy in the treatment of acute mastitis.

In pigs, the product is indicated for use as an adjunctive therapy in the treatment of swine respiratory diseases.

4.3 Contraindications

Do not exceed the recommended dose or the duration of treatment.

Do not administer to pregnant mares.

Do not administer to pregnant sows, gilts at mating and in breeding boars.

Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, where there is evidence of a blood dyscrasia or hypersensitivity to the product.

Do not use in dehydrated animals suffering from ileus-associated colics.

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 or colic should be determined and treated with appropriate concomitant therapy.

Non-steroidal anti-inflammatory drugs are not permitted under the Rules of Racing and under rules covering other competitive events. Horses intended for racing and competition should be prevented from racing or competing when in need of treatment and horses which have been recently treated should be dealt with according to local requirements. Appropriate precautions must be taken to ensure compliance with competition regulations.

Cattle should be treated with flunixin in conjunction with disease-specific therapy and an improvement in housing conditions.

The use of flunixin in conjunction with disease-specific antibiotic therapy may mask antibiotic resistance of the bacteria, due to alleviation of inflammation symptoms.

4.5 Special precautions for use

[i] 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.

Do not use in piglets weighing less than 6 kg.

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.

Due to the excipient propylene glycol, life-threatening shock reactions may occur in rare cases. The solution for injection should therefore be injected slowly and be of approximate body temperature.

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 fetal membranes resulting in retained placentae.
See also section 4.7.

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.

[ii] Special precautions to be taken by the person administering the veterinary medicinal product to animals

The veterinary medicinal product can cause skin and eye irritation. Avoid contact with skin and eyes. In case of accidental skin exposure, wash the affected area immediately with plenty of water. In case of accidental eye contact, rinse immediately with plenty of water. If skin and/or eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.

The veterinary medicinal product can cause hypersensitivity (allergy) reactions. People with known hypersensitivity to non-steroidal anti-inflammatory drugs should avoid contact with the veterinary medicinal product. Adverse reactions can be serious. Gloves should be worn during application.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

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

Rare cases of anaphylactic reaction have been reported. In horses (rare) and cattle (very rare) anaphylaxis type reactions can include neurological signs such as convulsion, loss of consciousness and ataxia. Such reactions may be exacerbated by intra-arterial injection.

In pigs (very rare), transient irritation may occur at the injection site, this resolves spontaneously within 14 days.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

May be used in pregnant and lactating cattle.

Do not administer to pregnant mares. Do not administer to pregnant sows, gilts at mating and in breeding boars. Safety studies in pregnant mares or sows have not been conducted.

The product should not be used in lactating sows.

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 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. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.

Concurrent administration of potentially nephrotoxic drugs should be avoided.

4.9 Amounts to be administered and administration route

For intravenous administration to cattle and horses and intramuscular injection to pigs.

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 other conditions 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.

PIGS For use in pigs, the recommended dose rate is 2 ml per 45 kg bodyweight (equivalent to 2.2 mg flunixin/kg) once by intramuscular injection, in the neck, in conjunction with appropriate antimicrobial therapy. The injection volume should be limited to a maximum of 5 ml per injection site.

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 recommended dose or duration of treatment.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

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

Overdose studies in the target species have shown the product to be well tolerated. Overdosage is associated with gastrointestinal toxicity.

4.11 Withdrawal period(s)

Cattle: Meat & offal: 7 days
Milk: 36 hours

Horses: Meat & offal: 7 days

Pigs: Meat & offal: 22 days

Do not use in mares producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

ATCvet Code: QM01 AG90
Pharmacotherapeutic group: Non-steroidal anti-inflamammatory

5.1 Pharmacodynamic 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.
The product has been shown to have some benefit in the treatment of experimental acute pulmonary emphysema (fog fever).

5.2 Pharmacokinetic particulars

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, C_{max} was 12.59 µg/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, C_{max} was 15.55 µg/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 PARTICULARS

6.1 List of excipients

Sodium Formaldehyde Sulphoxylate
Disodium Edetate
Phenol
Propylene Glycol
Sodium hydroxide
Hydrochloric Acid
Water for Injections

6.2 Major Incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

Following withdrawal of the first dose use the product within 28 days. Discard unused product.

6.4 Special precautions for storage

Do not store above 25°C. Keep the vial in the outer carton to protect from light.

6.5 Nature and composition of immediate packaging

This product is supplied in 50 ml, 100 ml and 250 ml clear colourless glass vials, complete with bromobutyl bungs and aluminium caps.
The product is also presented in packs of 5, 10 and 12 vials for the 50 ml and 100 ml and packs of 5 vials for the 250 ml, each vial will be provided in an individual carton which will in turn be packed into a plain brown outer cardboard containing the specified number of vials.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
Northern Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 02000/4170

9. DATE OF FIRST AUTHORISATION

26 November 1998

10. DATE OF REVISION OF THE TEXT

June 2023

Approved: 02 June 2023