SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pyroflam 50 mg/mL Solution for Injection for Cattle, Horses and Pigs

2. QUALITATION AND QUANTITATIVE COMPOSITION

Each mL contains:

Active substance:

Flunixin (as flunixin meglumine) 50 mg
(equivalent to 83 mg flunixin meglumine)

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Phenol	5 mg
Sodium Formaldehyde Sulphoxylate Dihydrate	2.5 mg
Disodium Edetate	
Propylene Glycol	
Sodium Hydroxide	
Hydrochloric Acid	
Water for Injection	

A clear colourless solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.
Horses.
Pigs.

3.2 Indications for use for each target species

In horses:
- alleviation of inflammation and pain associated with musculo-skeletal 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.

In pigs:
Adjunctive therapy in the treatment of swine respiratory diseases.

3.3 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 the active substance, other NSAIDs or to 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 veterinary medicinal product within 48 hours before expected parturition in cows.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.
Do not use in piglets weighing less than 6 kg.
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 veterinary medicinal product in the immediate post- partum period may interfere with uterine involution and expulsion of foetal membranes resulting in retained placentae.

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

- The veterinary medicinal product may cause reactions in sensitive individuals. People with known hypersensitivity to non-steroidal anti-inflammatory products and/or to polyethylene glycol should not handle the veterinary medicinal product. Reactions may be serious.
- To avoid possible sensitisation reactions, avoid contact with the skin. Personal protective equipment consisting of gloves should be worn when handling this veterinary medicinal product.
- In case of skin contact, wash exposed area with plenty of water and soap. If symptoms persist seek medical advice.
- Avoid eye contact. In the case of accidental contact with eyes, rinse immediately with plenty of water and seek medical advice.
- Avoid accidental self-injection. 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.

Special precautions for the protection of the environment:

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.

3.6 Adverse events

Cattle, horses

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylaxis[1]; Neurological signs[1] (such as Convulsion, Loss of consciousness and Ataxia);
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Digestive tract disorder (Gastrointestinal irritation, Gastrointestinal ulceration); Renal disorder[2] ; Hepatic disorder[3] ;

[1] Very rare frequency in cattle. May be exacerbated by intra-arterial injection.
[2] Especially in dehydrated or hypovolaemic animals.
[3] Idiosyncrasic reactions

Pigs.

Undetermined frequency (cannot be estimated from the available data):	Injection site irritation[1]; Digestive tract disorder (Gastrointestinal irritation, Gastrointestinal ulceration); Renal disorder[2] ; Hepatic disorder[3] ;

[1] Transient. Resolves spontaneously within 14 days.
[2] Especially in dehydrated or hypovolaemic animals.
[3] Idiosyncrasic reactions

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation in 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 veterinary medicinal 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.

3.8 Interactions 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, 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 veterinary medicinal 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).

3.9 Administration routes and dosage

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 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.

For intramuscular injection to pigs.

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.

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Overdosage is associated with gastrointestinal toxicity.

3.11 Special restrictions for use and special conditions for 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.

3.12 Withdrawal periods

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

Horses: Meat and offal: 10 Days
Milk: The veterinary medicinal product is not authorised for use in lactating mares producing milk for human consumption.

Pigs: Meat and offal: 22 Days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet Code:

QM01AG90

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

In an experimental study, flunixin was administered intravenously to pigs as a single dose of 2.0 mg/kg. Flunixin was >98% protein bound at all physiologically relevant concentrations, but also had a large volume of distribution at steady-state. All plasma concentrations were below the limit of quantitation (0.02 µg/mL) by 48 hours and the elimination half-life was 7.76 hours.

Environmental properties

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not store above 25°C.
Keep container in the outer carton in order to protect from light.
Avoid introduction of contamination.
Discard unused product.

5.4 Nature and composition of immediate packaging

Container: Type I clear colourless glass vial.
Closure: bromobutyl bungs and aluminium caps

1 carton x 50 mL vial
1 carton x 100 mL vial
1 carton x 250 mL vial

Not all pack sizes may be marketed.

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

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collections systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited

7. MARKETING AUTHORISATION NUMBER

Vm 02000/4253

8. DATE OF FIRST AUTHORISATION

23 February 2006

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

April 2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 30 July 2025