1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Flunixin Injection, 50mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active Substance:
Flunixin (as flunixin meglumine) 50 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Phenol	5.0 mg
Sodium Formaldehyde Sulphoxylate Dihydrate	2.5 mg
Disodium Edetate	
Sodium Hydroxide	
Propylene Glycol	
Hydrochloric Acid	
Water for Injections	

A clear colourless solution for injection.

3 CLINICAL INFORMATION

3.1 Target Species

Cattle, horses and pigs.

3.2 Indications for use for each target species

The veterinary medicinal product is indicated for use in cattle and horses in the alleviation of inflammation and pain.

In the horse, the veterinary medicinal product is indicated for the alleviation of inflammatory signs associated with musculo-skeletal disorders and for the alleviation of visceral pain associated with colic.

In cattle, the veterinary medicinal product is indicated for the control of acute inflammation associated with respiratory disease. The veterinary medicinal product has also been shown to have some benefit in the treatment of acute pulmonary emphysema (fog fever) and as adjunctive therapy in the treatment of acute mastitis.

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

3.3 Contraindications

Do not exceed the recommended dose or duration of treatment. Do not administer to pregnant mares.

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.

3.4 Special warnings

The cause of the underlying inflammatory condition or colic 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 animals less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided animals may require careful clinical management.

Avoid use in any dehydrated, hypovalaemic 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.

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 veterinary medicinal product to animals:

Flunixin meglumine is irritating to the eye. Avoid contact with the skin and splashes to the eye.

Special precautions for the protection of the environment:

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

3.6 Adverse events

Cattle, horses and pigs:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Gastrointestinal irritation, Ulceration; Renal disorder[1]

1In dehydrated or hypovolaemic animals.

Horses and calves:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Collapse[2]

2Following rapid intravenous injection.

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 in pregnancy and lactation in cattle.
Do not use in pregnant mares or pregnant sows. Safety studies in pregnant mares or pregnant sows have not been conducted.

3.8 Interaction with other medicinal products and other forms of interactions

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.

3.9 Administration routes and dosage

The veterinary medicinal product is indicated 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.
During clinical trials, approximately 10% of the horses required one or two additional treatments. The cause of colic should be determined and treated with concurrent therapy.

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.

Cattle:
For use in acute inflammatory conditions, 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 2.2 mg flunixin/kg bodyweight equivalent to 2 ml per 45 kg bodyweight once by intramuscular injection. The veterinary medicinal product should be administered as adjunctive therapy in conjunction with a suitable course of antibacterial therapy.

Do not puncture the stopper more than 25 times.

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

In common with other drugs in this class, overdose 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

Horses:
Meat and offal: 7 days.
Not authorised for use in mares producing milk for human consumption.

Pigs:
Meat and offal: 24 days.

Cattle:
Meat and offal: 7 days.
Milk: 36 hours.

Animals must not be slaughtered for human consumption during treatment. Milk for human consumption must not be taken during treatment.

4 PHARMACOLOGICAL INFORMATION

4.1 ATCvet code
ATC vet 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 E_2 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
anti-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 micrograms/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 micrograms/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.

5 PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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. Protect from light.

5.4 Nature and composition of immediate packaging

The veterinary medicinal product is supplied in 50ml and 100ml type I clear glass vials, complete with bromobutyl bungs and aluminium caps.

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 or household waste.

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 collection systems applicable to the veterinary medicinal product concerned.

6 NAME OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited

7 MARKETING AUTHORISATION NUMBER(S)

VPA22664/046/001

8 DATE OF FIRST AUTHORISATION

23 April 1997

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

22 January 2024

10 CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).