Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Flunixin Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Flunixin (as flunixin meglumine)	50 mg/ml

Excipients

Phenol	5.0 mg/ml
Sodium formaldehyde Sulphoxylate Dihydrate	2.5 mg/ml

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

A sterile aqueous solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, horses and pigs

4.2 Indications for use, specifying the target species

Flunixin Injection is indicated for use in cattle and horses in the alleviation of inflammation and pain.

In the horse, Flunixin Injection 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, Flunixin Injection is indicated for the control of acute inflammation associated with respiratory disease. Flunixin Injection 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, Flunixin Injection is indicated as an adjunctive therapy in the treatment of swine respiratory diseases.

4.3 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.

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.

4.5 Special precautions for use

Special precautions for use in animals

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.

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.

4.6 Adverse reactions (frequency and seriousness)

For this class of drug, untoward effects include gastrointestinal irritation, ulceration and, in dehydrated or hypovolaemic animals, potential for renal damage.
There are occasional reports of collapse following rapid intravenous injection in horses and calves.

4.7 Use during pregnancy, lactation or lay

Flunixin Injection may be used in pregnant and lactating cattle.
Do not administer Flunixin Injection to pregnant mares or pregnant sows. Safety studies in pregnant mares or pregnant sows have not been conducted.

4.8 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.

4.9 Amounts to be administered and administration route

Flunixin Injection 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. Flunixin Injection should be administered as adjunctive therapy in conjunction with a suitable course of antibacterial therapy.

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

In common with other drugs in this class, overdose is associated with gastrointestinal toxicity.

4.11 Withdrawal period(s)

Meat: Animals must not be slaughtered for human consumption during treatment. Horses and cattle intended for human consumption may be slaughtered 7 days following treatment. Pigs intended for human consumption may be slaughtered 24 days following treatment.

Milk for human consumption must not be taken during treatment.Milk: 36 hours. Milk intended for human consumption may only be taken from treated cows after 36 hours from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: non-steroidal anti-inflammatory drug
ATC vet code: QM01AG90

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 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.

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 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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Sodium formaldehyde sulphoxylate dihydrate
Disodium Edetate
Sodium hydroxide
Propylene Glycol
Hydrochloric Acid
Water for Injections

6.2 Major incompatibilities

None known.

6.3 Shelf-life

3 years. Following withdrawal of the first dose the product should be used within 28 days.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

Flunixin Injection is supplied in 50ml and 100ml type I clear glass vials, complete with bromobutyl bungs and aluminium caps.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/046/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23rd April 1997
Date of last renewal: 22nd April 2007

10 DATE OF REVISION OF THE TEXT

August 2019