Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Flunixin 25 mg/g Granules for Horses

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 g sachet contains:
Active Substance
Flunixin 250 mg
(as flunixin meglumine)
Excipients
For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Granules.
White to cream coloured granules.

4 CLINICAL PARTICULARS

4.1 Target Species

Horses.

4.2 Indications for use, specifying the target species

For the alleviation of inflammation and pain associated with musculo-skeletal disorders.

4.3 Contraindications

Do not use in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastrointestinal ulceration or bleeding or where there is evidence of a blood dyscrasia. Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special Precautions for use in animals

Do not exceed the recommended dose or the duration of treatment.
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 as there is a potential risk of increased renal toxicity.

Special precautions to be taken by the person administering the product to the animals

The product may cause hypersensitivity (allergy) in sensitive individuals. Reactions may be serious. People with known hypersensitivity to substances belonging to the non-steroidal anti-inflammatory group should avoid contact with the product.
To avoid possible sensitisation reactions, avoid contact with the skin. Impermeable gloves should be worn during application. In case of skin contact, wash exposed area with plenty of water and soap. If symptoms persist seek medical advice.
Avoid eye contact. Wear approved safety glasses when handling this product. In the case of accidental contact with eyes, rinse immediately with plenty of water and seek medical advice.
Avoid inhalation. Wear either a disposable half-mask respirator conforming to European Standard EN149 or a non-disposable respirator to European Standard EN140 with a filter to EN143 when handling the product. In case of inhalation, seek medical advice.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Adverse effects include gastrointestinal irritation, ulceration and, in dehydrated or hypovolaemic animals, potential for renal damage. If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

4.7 Use during pregnancy, lactation or lay

Studies in laboratory animals have shown evidence of foetotoxic effects of flunixin after oral administration (rabbit and rat) and intramuscular administration (rat) at maternotoxic doses as well as an increase in the gestation period. Studies to demonstrate safety in pregnant mares have not been conducted. Do not administer the product to pregnant mares.

4.8 Interaction with other medicinal products and other forms of interactions

Do not administer other non-steroidal anti-inflammatory drugs (NSAID) or glucocorticosteroids concurrently, or within at least 24 hours of administration of this product. The treatment-free period should take into account the pharmacokinetic properties of the products used. Concurrent use of other active substances that have a high degree of protein binding may compete with this product, which may lead to toxic effects.
Gastrointestinal tract ulceration may be exacerbated by corticosteroids in patients given NSAIDs.
Concurrent administration of potentially nephrotoxic drugs should be avoided.
It is preferable that NSAID's which inhibit prostaglandin synthesis are not administered to animals undergoing general anaesthesia until fully recovered.

4.9 Amounts to be administered and administration route

For oral administration only.
The dose rate is 1.1 mg flunixin per kg bodyweight i.e. one 10 g sachet per 227 kg (500 lb) bodyweight once daily for up to 5 consecutive days according to clinical response.

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible. This product is administered by sprinkling on a small amount of food. Add to feed immediately before administration. Discard any remaining medicated feed.

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

Overdose is associated with gastrointestinal toxicity.

4.11 Withdrawal period(s)

Meat and offal: 15 Days
Milk: Not permitted for use in lactating mares producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and antirheumatic products, non-steroids.
ATCvet Code: QM01AG90

5.1 Pharmacodynamic properties

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

Flunixin meglumine acts as a reversible non-selective inhibitor of cyclo-oxygenase (both COX 1 and COX 2 forms), 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. Although flunixin has no direct effect on endotoxins after they have been produced, it reduces prostaglandin production and hence reduces the many effects of the prostaglandin cascade. Prostaglandins are part of the complex processes involved in the development of endotoxic shock.

5.2 Pharmacokinetic particulars

After a single administration of the product to horses at 1.1 mg/kg of flunixin, maximum plasma concentration of flunixin (2.51 µg/ml) is reached in about 1 hour.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Povidone K30
Crospovidone
Pregelatinised starch (maize)
Lactose monohydrate
Sucrose
Peppermint flavour
Cellulose microcrystalline

6.2 Major incompatibilities

Not applicable.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf-life after incorporation into feed: Use immediately

6.4 Special precautions for storage

Do not store above 25° C. Keep the sachet in the outer carton.

6.5 Nature and composition of immediate packaging

Cartons of 10 laminated foil (C1S/LDPE/Alu/SP) sachetseach containing 10 g granules.

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 (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22664/092/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 November 2010
Date of last renewal: 08 January 2016

10 DATE OF REVISION OF THE TEXT

January 2019