# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norflunix 50 mg/ml solution for injection for pigs

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

**Active substance:**

| | |
|---|---|
| Flunixin | 50 mg |
| (equivalent to Flunixin meglumine | 82.9 mg) |

**Excipients:**

| | |
|---|---|
| Phenol | 5 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

Pigs.

### 4.2 Indications for use, specifying the target species

For alleviation of Mastitis-Metritis-Agalactia Syndrome (MMA) with appropriate antibiotic treatment to reduce clinical signs.

### 4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of excipients.
Do not use in animals suffering from hepatic, renal, or cardiac disease.
Do not use in animals with lesions of the gastrointestinal tract (for example gastro-intestinal ulceration or bleeding).
Do not use when there is evidence of blood dyscrasia.
Do not use in dehydrated, hypovolaemic or hypotensive animals.

## 4.4 Special warnings for each target species

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

## 4.5 Special precautions for use

Special precautions for use in animals

Use of the product in the immediate postpartum period may interfere uterine involution in the expulsion of the fetal membranes resulting in a retention placenta. Ensure that the expulsion of the placenta occurred before administering the product.

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

In case of accidental spillage onto skin wash immediately with water.

Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product.

People with known hypersensitivity to non-steroidal anti-inflammatory products should avoid contact with the veterinary medicinal product.

## 4.6 Adverse reactions (frequency and seriousness)

Flunixin meglumine is a non steroidal anti-inflammatory drug (NSAID). Untoward effects include gastrointestinal irritation, ulceration and, especially in dehydrated or hypovolaemic animals, potential for renal damage.
In pigs, transient irritation may occur at the injection site.

## 4.7 Use during pregnancy, lactation or lay

Do not use during the whole or part of the pregnancy.

## 4.8 Interaction with other medicinal products and other forms of interaction

Do not administer other non-steroidal anti-inflammatory drug (NSAID) 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.

## 4.9 Amounts to be administered and administration route

Intramuscular use.

The veterinary medicinal product should be administered at a dosage rate of 2.2 mg flunixin/kg bodyweight (2 ml/45 kg) by deep intramuscular injection. Flunixin should not be injected in adipose tissue. One or two injections can be administered separated by a 12 hour interval.
The number of treatments to be administered (one or two) will be according to clinical response.
The volume administered per injection site should not exceed 3ml.

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

Flunixin meglumine is a non-steroidal anti-inflammatory drug. Overdose is associated with gastrointestinal toxicity.

## 4.11 Withdrawal period

Meat: 24 days.

# 5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non steroids
ATC vet 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 $E_2$ synthesis in the hypothalamus. Although flunixin has not a direct effect on endotoxins once they have been produced, it reduces the production of prostaglandins and therefore reduces the majority of its effects. Prostaglandins belong to the complex processes involved in the endotoxic shock development.

## 5.2 Pharmacokinetic particulars

In pigs, after intramuscular administration of 2.2 mg of flunixin meglumine/kg, a peak plasma concentration round 3 µg/ml is detected approximately 20 minutes after injection. The bioavailability, expressed as a fraction of the dose absorbed was found to be 93%.

The volume of distribution was 2 l/kg, while the elimination half-life was 3.6 hours. Excretion (as most drug unchanged) occurred primarily in the urine, but also detected in the faeces.

## 6. PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Sodium formaldehyde sulphoxylate dihydrate
Disodium edetate dihydrate
Phenol
Propylene glycol
Diethanolamine
Hydrochloric acid
Water for injections

### 6.2 Incompatibilities

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

### 6.3 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.

### 6.4 Special precautions for storage

Store below 25°C.
Protect from light.
Avoid introduction of contamination. Discard unused product.

### 6.5 Nature and composition of immediate packaging

50 ml, 100 ml and 250 ml type I clear colourless glass vials, 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

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

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 15 April 2003.
Date of the last renewal: 31 July 2013.

## 10 DATE OF REVISION OF THE TEXT

## PROHIBITION OF SALE, SUPPLY AND/OR USE

To be supplied only on veterinary prescription.