PACKAGE LEAFLET FOR:
Norflunix 50 mg/ml solution for injection for pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder and manufacturer responsible for batch release:
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry, Co. Down
BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norflunix 50 mg/ml solution for injection for pigs
Flunixin meglumine

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

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

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

4. INDICATION(S)

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

5. 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.

6. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigs

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

Flunixin should not be injected in adipose tissue. One or two injections can be administered separate 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.

10. WITHDRAWAL PERIOD

Meat: 24 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and label after EXP.

Shelf life after first opening the immediate packaging: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:

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

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 this 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.

Use during pregnancy, lactation or lay:

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

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.

Overdose (symptoms, emergency procedures, antidotes):

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

Incompatibilities:

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD month YYYY

15. OTHER INFORMATION

Multidose vials of 50, 100 and 250 ml.
Not all pack sizes may be marketed.

For animal treatment only.
To be supplied only on veterinary prescription.