SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norixin 5% Solution for 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 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***: Cattle and Horses

4.2 ***Indications for use, specifying the target species:***

In the horse, the product is indicated for the alleviation of inflammation associated with acute musculo-skeletal disorders.

In cattle, the product is indicated as an adjunct to antimicrobial therapy to reduce clinical signs of acute inflammation in cases of infectious respiratory disease.

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 (caused by endoparasites, for example), where there is evidence of a blood dyscrasia or hypersensitivity to the product.

4.4 ***Special Warnings for Each Target Species:***

Horses intended for racing and competition should be prevented from racing or competing when in need of treatment and horses which have been recently treated should be dealt with according to local requirements. Appropriate precautions must be taken to ensure compliance with competition regulations.

4.5 ***Special Precautions for Use:***

(i) Special precautions for use in animals:
Do not exceed the recommended dose or the duration of treatment.

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

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.

It is preferable that NSAIDs, which inhibit prostaglandin synthesis are not administered to animals undergoing general anaesthesia until fully recovered.

Due to the excipient, propylene glycol, life-threatening collapse can occur in rare cases. The product has therefore to be injected slowly and should be used at body temperature. Administration should be stopped immediately if signs of intolerance occur and, if necessary, treatment for shock initiated.

During treatment, an adequate water supply should be provided.

(ii) Special precautions to be taken by the person administering the product to the animals:
In case of spillage onto skin wash immediately with water.

To avoid possible sensitisation reactions, avoid contact with the skin. Gloves should be worn during application.

The product may cause reactions in sensitive individuals. If you have known hypersensitivity for non-steroidal anti-inflammatory products do not handle the product. Reactions may be serious.

4.6 ***Adverse reactions (frequency and seriousness):***

Untoward effects include the possibility of bleeding, gastrointestinal irritation and ulceration, particularly in ponies, papilliary necrosis of the kidney and changes in haematology.
In rare cases, anaphylactoid reactions have been observed which were sometimes fatal.

4.7 ***Use during pregnancy, lactation or lay:***

Do not administer the product to pregnant animals. Safety studies in pregnant animals have not been conducted.

4.8 *Interactions with other medicinal products and other forms of interaction:*

Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given non- steroidal anti-inflammatory drugs.
Do not administer NSAIDs or corticosteroids 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.
Because of the risk of renal injury, do not use concomitantly with methoxyfluran.

4.9 *Amount to be administered and administration route:*

The product is indicated for intravenous administration to cattle and horses.

HORSES: 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 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 3 consecutive days.
As flunixin can produce a therapeutic effect in cattle due to its anti- inflammatory activity, resistance towards the causal (i.e. antibiotic) therapy may be masked.

Avoid introduction of contamination. The stopper should not be punctured more than 50 times

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

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

4.11 *Withdrawal periods:*

Cattle, meat and offal:	14 days
Horse, meat and offal:	28 days
Cattle, milk:	48 hours

Not permitted for use in lactating mares producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

ATCvet Code:
QM01 AG90
Pharmacotherapeutic group: Non-steroidal anti-inflamammatory

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.

5.2 *Pharmacokinetics properties*

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 µg/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 µg/ml and the elimination half-life was approximately 4 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 *List of excipients:*

Sodium Formaldehyde Sulphoxylate
Phenol
Disodium Edetate
Propylene Glycol
Sodium Hydroxide
Hydrochloric Acid
Water for Injections

6.2 *Major Incompatabilities:*

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

6.3 ***Shelf-Life:***

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

Following withdrawal of the first dose use the product within 28 days. Discard unused product.

6.4 ***Special Precautions for Storage:***

Do not store above 25°C. **Keep container in the outer carton to protect from light**.

6.5 ***Nature and composition of immediate packaging:***

50 ml, 100 ml and 250 ml Type I clear colourless glass vials, complete with bromobutyl bungs and aluminium caps.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste material 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

Vm 02000/4137

9. DATE OF FIRST AUTHORISATION

31 October 1997

10. DATE OF REVISION OF THE TEXT

18 November 2019

Approved 18 November 2019