DRAFT LABEL

Norixin 5% Solution for Injection
(50mg Flunixin)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norixin 5% Solution for Injection
flunixin (as flunixin meglumine)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
50 mg flunixin, as flunixin meglumine
5 mg phenol as preservative
2.5 mg Sodium Formaldehyde Sulphoxylate Dihydrate

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle and Horses

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle: Milk – 48 hours; Meat and Offal - 14 days
Horses: Meat and Offal - 28 days.
Not permitted for use in lactating mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

See package leaflet for Operator warnings.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep container in outer carton to protect from light. Following withdrawal of the first dose use the product within 28 days.

Once broached, use by:_____

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, if applicable

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:
(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Newry, Co. Down
Northern Ireland

Distributed by:

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4137

17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

DRAFT CARTON

Norixin 5% Solution for Injection
(50mg Flunixin)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flunixin 5% Solution for Injection [AT, FI, IT, ES]
Fluniveto 5% Solution for Injection [BE]
Paraflunix 5% Solution for Injection [DE]
Flunixin / Norbrook 5% Solution for Injection [EL]
Fluniveto 5% Solution for Injection [LU]
Flunixina 5% Solution for Injection [PT]
Norixin 5% Solution for Injection [UK]
flunixin (as flunixin meglumine)

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:

Flunixin, as flunixin meglumine	50 mg
Phenol, as preservative	5 mg
Sodium Formaldehyde Sulphoxylate Dihydrate	2.5 mg

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle and Horses

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use
Operator warnings – see package leaflet

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Keep container in the outer carton to protect from light.
Following withdrawal of the first dose, use the product within 28 days.

Once broached, use by:_____

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, if applicable

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Marketing Authorisation Holder:

(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Newry, Co. Down Northern Ireland

Distributed by:

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4137

17. MANUFACTURER'S BATCH NUMBER

B.N.:

LOGO

PACKAGE LEAFLET

Norixin 5% Solution for Injection
(50mg Flunixin)

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

Marketing authorisation holder:
(EU)
Norbrook Laboratories (Ireland) Limited
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Station Works
Camlough Road, Newry,
Co. Down, BT35 6JP
Northern Ireland

Manufacturing Authorisation Holder Responsible for Batch Release:
(EU)
Norbrook Manufacturing Ltd
Rossmore Industrial Estate
Monaghan
Ireland

(UK)
Norbrook Laboratories Limited
Station Works
Camlough Road, Newry,
Co. Down, BT35 6JP
Northern Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Norixin 5% Solution for Injection
flunixin (as flunixin meglumine)

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

Each ml contains:

Flunixin, as flunixin meglumine	50 mg
Phenol, as preservative	5 mg
Sodium Formaldehyde Sulphoxylate Dihydrate	2.5 mg

A clear colourless solution

4. INDICATION(S)

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

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.

5. 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.
Do not use in lactating mares producing milk for human consumption.

6. ADVERSE REACTIONS

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.

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

7. TARGET SPECIES

Cattle and Horses

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

Norixin Injection 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 by intravenous injection, 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 injected intravenously and

repeated 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.

9. ADVICE ON CORRECT ADMINISTRATION

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

This medicinal product must not be mixed with other medicinal products.

Avoid introduction of contamination.

The stopper should not be punctured more than 50 times. A draw off needle should be used to avoid excessive puncturing of the stopper.

10. WITHDRAWAL PERIOD

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.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Keep container in the outer carton to protect from light.
Keep out of the reach and sight of children
Following withdrawal of the first dose, use the product within 28 days. Discard unused product.
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

Do not use after the expiry date stated on the carton and label after EXP

12. SPECIAL WARNINGS

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.
Avoid use in any dehydrated, hypovolemic or hypotensive animal.
Do not administer to pregnant animals.

Do not exceed the recommended dose or the duration of treatment.
Avoid intra-arterial injection.
It is preferable that NSAIDs, which inhibit prostaglandin synthesis, are not administered to animals undergoing general anaesthesia until fully recovered.
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.
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.
Use in any animal less than 6 weeks of age or in aged animals may involve an additional risk. If such use cannot be avoided animals may require a reduced dosage and careful clinical management.
During treatment, an adequate water supply should be provided.
The cause of the underlying inflammatory condition should be determined and treated with appropriate concomitant therapy.
Concurrent administration of potentially nephrotoxic drugs should be avoided.
Because of the risk of renal injury do not use concomitantly with methoxyfluran.
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.
Flunixin meglumine is a non-steroidal anti-inflammatory drug. Overdosage is associated with gastrointestinal toxicity.
In the absence of incompatibility studies, this medicinal product must not be mixed with other medicinal products.

OPERATOR WARNINGS:
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.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

June 2019

15. OTHER INFORMATION

Packaging quantities:
Multi-dose vials of 50 ml, 100 ml and 250 ml.
Not all pack sizes may be marketed.

Vm 02000/4137

Approved: 21 June 2019