# DRAFT LABEL

# FLUNIXIN 25 mg/g GRANULES FOR HORSES

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equinixin 25mg/g Granules for Horses (UK, DE)
Flunixin 25mg/g Granules for Horses
Flunixine Granules 25mg/g for Horses (FR)
Flunixin vet 25 mg/g Granules for Horses (FI)
Flunimeg 250mg Granules for Horses (DK)
Flunixin N-vet 25 mg/g Granules for Horses (SE)
Flunixin (as flunixin meglumine)

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

White to cream coloured granules containing 250 mg flunixin, as flunixin meglumine per 10g sachet.

## 3. PHARMACEUTICAL FORM

Granules

## 4. PACKAGE SIZE

10 gram

## 5. TARGET SPECIES

Horses.

## 6. INDICATION(S)

***Only for those countries where the product is available without prescription:***

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

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only.

Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

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

## 9. SPECIAL WARNINGS

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP: DD/MM/YY
Shelf-life after addition to feed: Use immediately

## 11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet

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

**For animal treatment only.**

POM-V To be supplied only on veterinary prescription

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

**Keep out of the sight and reach of children.**

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited,
Station Works,
Camlough Road,
Newry,

County Down,
Northern Ireland
BT35 6JP

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4241
ManA 2000

## 17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

**DRAFT LABEL**

# FLUNIXIN 25 mg/g GRANULES FOR HORSES

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equinixin 25mg/g Granules for Horses (UK, DE)
Flunixin 25mg/g Granules for Horses
Flunixine Granules 25mg/g for Horses (FR)
Flunixin vet 25 mg/g Granules for Horses (FI)
Flunimeg 250mg Granules for Horses (DK)
Flunixin N-vet 25 mg/g Granules for Horses (SE)
Flunixin (as flunixin meglumine)

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

White to cream coloured granules containing 250 mg flunixin, as flunixin meglumine per 10g sachet.

## 3. PHARMACEUTICAL FORM

Granules

## 4. PACKAGE SIZE

10 gram

## 5. TARGET SPECIES

Horses.

## 6. INDICATION(S)

***Only for those countries where the product is available without prescription:***

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

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration only.

Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

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

## 9. SPECIAL WARNINGS

Read the package leaflet before use.

## 10. EXPIRY DATE

EXP: DD/MM/YY
Shelf-life after addition to feed: Use immediately

## 11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet

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

**For animal treatment only.**

POM-V To be supplied only on veterinary prescription

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

**Keep out of the sight and reach of children.**

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Norbrook Laboratories Limited,
Station Works,
Camlough Road,
Newry,
County Down,
Northern Ireland
BT35 6JP

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4241
ManA 2000

## 17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

# PACKAGE LEAFLET

# FLUNIXIN 25 mg/g GRANULES FOR HORSES
# (250mg Flunixin)

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

Marketing Authorisation Holder

Norbrook Laboratories Limited,
Station Works, Camlough Road,
Newry,
County Down,
Northern Ireland
BT35 6JP

Manufacturer of the Batch Release
Norbrook Manufacturing Ltd.
Rossmore Industrial Estate
Monaghan
Ireland

Norbrook Laboratories Limited
Station Works
Newry
Co. Down
BT35 6JP
Northern Ireland

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equinixin 25mg/g Granules for Horses (UK, DE)
Flunixin 25mg/g Granules for Horses
Flunixine Granules 25mg/g for Horses (FR)
Flunixin vet 25 mg/g Granules for Horses (FI)
Flunimeg 250mg Granules for Horses (DK)
Flunixin N-vet 25 mg/g Granules for Horses (SE)
Flunixin (as flunixin meglumine)

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

Each 10 g sachet contains:

***Active Substance***
Flunixin 250 mg
(as flunixin meglumine)

White to cream coloured granules

## 4. INDICATION(S)

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

## 5. 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.

## 6. ADVERSE REACTIONS

Adverse effects include gastrointestinal irritation, ulceration and, in dehydrated or hypovolaemic animals, potential for renal damage.
If you notice any serious effects or effects not mentioned in this leaflet, please inform your veterinary surgeon. If adverse reactions occur, treatment should be discontinued and the advice of a veterinarian should be sought.

## 7. TARGET SPECIES

Horses

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

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.

## 9. ADVICE ON CORRECT ADMINISTRATION

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.

## 10. WITHDRAWAL PERIOD

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

## 11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after "EXP".
Keep out of the sight and reach of children
Keep the sachet in the outer carton.
Shelf-life after addition to feed: Use immediately

## 12. SPECIAL WARNING(S)

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."

Pregnancy and lactation:

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.

Interaction with other medicinal products and other forms of interaction:

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.

Overdose (symptoms, emergency procedures, antidotes):

Overdose is associated with gastrointestinal toxicity.

**USER WARNINGS**

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.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, if any

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## 14. DATE ON WHICH THE PACKAGE INSERT WAS LAST REVISED

June 2019

## 15. OTHER INFORMATION

POM-V To be supplied only on veterinary prescription

**For Animal Treatment Only**

Cartons of 10 sachets, each sachet containing 250 mg of Flunixin.

Vm 02000/4241
ManA 2000

**DISTRIBUTED BY:**

Norbrook Laboratories (GB) Limited
1 Saxon Way East
Oakley Hay Industrial Estate
Corby
Northamptonshire
NN18 9EX
United Kingdom

Approved 16 September 2019