# DRAFT CARTON
# PYROFLAM 50MG/ML SOLUTION FOR INJECTION FOR CATTLE, HORSES AND PIGS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PYROFLAM 50MG/ML SOLUTION FOR INJECTION FOR CATTLE, HORSES AND PIGS

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Flunixin (as meglumine) 50 mg/ml
Sodium Formaldehyde Sulphoxylate Dihydrate 2.5 mg/ml
Phenol 5 mg/ml as antimicrobial preservative.

## 3. PHARMACEUTICAL FORM

Solution for injection

## 4. PACKAGE SIZE

50 ml, 100 ml and 250 ml vials

## 5. TARGET SPECIES

Cattle, Horses and Pigs

## 6. INDICATION(S)

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

Pyroflam Injection is indicated for intravenous administration to cattle and horses.

HORSES: For use in equine colic, the recommended dose rate is 1.1 mg flunixin/kg bodyweight equivalent to 1 ml per 45 kg bodyweight by intravenous injection. Treatment may be repeated once or twice if colic recurs.

For use in musculo-skeletal disorders, the recommended dose rate is 1.1 mg flunixin/kg bodyweight equivalent to 1 ml per 45 kg bodyweight, injected intravenously once daily for up to 5 days according to clinical response.

For the treatment of endotoxaemia or septic shock associated with gastric torsion and other conditions in which the circulation of blood to the gastrointestinal tract is compromised: 0.25 mg/kg (1 ml per 200 kg) every 6-8 hours.

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 5 consecutive days.

Pyroflam Injection is indicated for intramuscular injection to pigs.

PIGS The recommended dose rate is 2 ml per 45 kg bodyweight (equivalent to 2.2 mg flunixin/kg) once by intramuscular injection, in the neck, in conjunction with appropriate antimicrobial therapy. The injection volume should be limited to a maximum of 5 ml per injection site.

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

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

## 8. WITHDRAWAL PERIOD

| | | |
|---|---|---|
| Cattle: | Meat and offal: | 10 Days |
| | Milk: | 24 Hours |
| Horses: | Meat and offal: | 10 Days |
| | Milk: | The product is not authorised for use in lactating mares producing milk for human consumption. |
| Pigs: | Meat and offal: | 22 Days |

## 9. SPECIAL WARNING(S), IF NECESSARY

***TARGET SPECIES WARNINGS****: Read the package leaflet before use.*

**USER WARNINGS:**

See package leaflet

## 10. EXPIRY DATE

EXP: DD/MM/YY

## 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.
Discard unused material.
When the container is broached for the first time, using the in-use shelf-life which is specified above, 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. Use of a draw-off needle is recommended to avoid excess broaching of the stopper

Avoid introduction of contamination.

## 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.**

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**

POM-V To be supplied only on veterinary prescription

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

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

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

**Marketing Authorisation Holder:**
Norbrook Laboratories Limited
Newry, Co. Down
United Kingdom

**Distributed by:**
NORBROOK LABORATORIES LIMITED
CARNBANE INDUSTRIAL ESTATE
NEWRY
CO. DOWN
BT35 6QQ
NORTHERN IRELAND

## 16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4253

## 17. MANUFACTURER'S BATCH NUMBER

B.N.:

LOGO

**DRAFT LABEL**
**PYROFLAM 50 mg/ml Solution for Injection for Cattle, Horses and Pigs**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pyroflam 50 mg/ml Solution for Injection for **Cattle, Horses and** Pigs

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

| | |
|---|---|
| Flunixin (as meglumine) | 50 mg/ml |
| Sodium formaldehyde sulphoxylate dihydrate | 2.5 mg/ml |

Phenol 5 mg/ml as antimicrobial preservative.

## 3. PHARMACEUTICAL FORM

Solution for injection

## 4. PACKAGE SIZE

50 ml, 100 ml and 250 ml vials

## 5. TARGET SPECIES

Cattle, Horses and Pigs.

## 6. INDICATION(S)

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION, SPECIAL WARNING(S)

Refer to package leaflet for full directions, warnings and user warnings

## 8. WITHDRAWAL PERIOD

| | |
|---|---|
| Cattle: | Meat and offal: 10 Days; Milk: 24 Hours |
| Horses: | Meat and offal: 10 Days |
| Pigs: | Meat and offal: 22 Days |

The product is not authorised for use in lactating mares producing milk for human consumption.

## 9. EXPIRY DATE

EXP: DD/MM/YY

## 10. 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, the product should be used within 28 days.

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

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

**Disposal: read package leaflet.**

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

**For animal treatment only.**

**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**

To be supplied only on veterinary prescription

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

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

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

**Manufacturer:**
Norbrook Laboratories Limited
Newry
Co. Down
United Kingdom

**Distributed by:**
Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

## 16. MARKETING AUTHORISATION NUMBER(S)

ManA 2000
Vm 02000/4253

## 17. MANUFACTURER'S BATCH NUMBER

B.N.:
DOM:

Date of broaching: ___/___/___
Date to discard: ___/___/___

# PACKAGE LEAFLET
# PYROFLAM 50mg/ml SOLUTION FOR INJECTION FOR CATTLE, HORSES AND PIGS

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

Norbrook Laboratories Limited
Newry, Co. Down
United Kingdom

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

**PYROFLAM 50mg/ml SOLUTION FOR INJECTION FOR CATTLE, HORSES AND PIGS**

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

| | |
|---|---|
| Flunixin (as meglumine) | 50 mg/ml |
| Sodium formaldehyde sulphoxylate dihydrate | 2.5 mg/ml |

Phenol 5 mg/ml as antimicrobial preservative.

## 4. INDICATION(S)

In horses:
- alleviation of inflammation and pain associated with musculo-skeletal disorders.
- alleviation of visceral pain associated with colic.
- adjunctive therapy in the treatment of endotoxaemia and septic shock.

In cattle:
- reduction of acute inflammation associated with respiratory disease.
- adjunctive therapy in the treatment of acute mastitis.

In pigs:
- adjunctive therapy in the treatment of swine respiratory diseases.

## 5. CONTRAINDICATIONS

Use is contraindicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, where there is evidence of a blood dyscrasia.

Do not use in case of hypersensitivity to flunixin meglumine, other NSAIDs or any of the excipients.

Do not use in case of haemorrhagic disorders.

Do not use in animals suffering from chronic musculo-skeletal disorders.

Do not administer to pregnant sows, gilts at mating and in breeding boars.

Do not use the product within 48 hours before expected parturition in cows.

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

## 6. ADVERSE REACTIONS

Flunixin meglumine is a non steroidal anti-inflammatory drug (NSAID). Untoward effects include gastrointestinal irritation, ulceration, hepatic idiosyncratic reactions, and, especially in dehydrated or hypovolaemic animals, potential for renal damage.
Overdosage is associated with gastrointestinal toxicity
In pigs, transient irritation may occur at the injection site, this resolves spontaneously within 14 days.

## 7. TARGET SPECIES

Cattle, Horses and Pigs

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

Pyroflam Injection is indicated for intravenous administration to cattle and horses.

HORSES: For use in equine colic, the recommended dose rate is 1.1 mg flunixin/kg bodyweight equivalent to 1 ml per 45 kg

bodyweight by intravenous injection. Treatment may be repeated once or twice if colic recurs.

For use in musculo-skeletal disorders, the recommended dose rate is 1.1 mg flunixin/kg bodyweight equivalent to 1 ml per 45 kg bodyweight, injected intravenously once daily for up to 5 days according to clinical response.

For the treatment of endotoxaemia or septic shock associated with gastric torsion and other conditions in which the circulation of blood to the gastrointestinal tract is compromised: 0.25 mg/kg (1 ml per 200 kg) every 6-8 hours.

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 5 consecutive days.

Pyroflam Injection is indicated for intramuscular injection to pigs.

PIGS: The recommended dose rate is 2 ml per 45 kg bodyweight (equivalent to 2.2 mg flunixin/kg) once by intramuscular injection, in the neck, in conjunction with appropriate antimicrobial therapy. The injection volume should be limited to a maximum of 5 ml per injection site.

## 9. ADVICE ON CORRECT ADMINISTRATION

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

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

Do not exceed the stated dose or duration of treatment.

## 10. WITHDRAWAL PERIOD

| | | |
|---|---|---|
| Cattle: | Meat and offal: | 10 Days |
| | Milk: | 24 Hours |
| Horses: | Meat and offal: | 10 Days |
| | Milk: | The product is not authorised for use in lactating mares producing milk for human consumption. |
| Pigs: | Meat and offal: | 22 Days |

## 11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Keep container in the outer carton to protect from light. Avoid introduction of contamination.

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

When the container is broached for the first time, using the in-use shelf-life which is specified above, 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. Use of a draw-off needle is recommended to avoid excess broaching of the stopper.

Keep out of the sight and reach of children.

## 12. SPECIAL WARNINGS

The cause of the underlying inflammatory condition should be determined and treated with appropriate concomitant therapy.
Avoid intra-arterial injection.
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 except in the case of endotoxaemia or septic shock.
It is preferable that NSAIDs, which inhibit prostaglandin synthesis are not administered to animals undergoing general anaesthesia until fully recovered.
Do not use in piglets weighing less than 6 kg.
NSAIDS are known to have the potential to delay parturition through a tocolytic effect by inhibiting prostaglandins that are important in signalling the initiation of parturition. The use of the product in the immediate post-partum period may interfere with uterine involution and expulsion of foetal membranes resulting in retained placentae.
May be used in pregnant and lactating cattle.
For pregnant mares, use only according to the benefit/risk assessment by the
Responsible Veterinarian.
Do not administer to pregnant sows, gilts at mating and in breeding boars.
The product should only be administered within the first 36 hours post-partum following a benefit/risk assessment performed by the responsible veterinarian and treated animals should be monitored for retained placentae.
Monitor drug compatibility closely where adjunctive therapy is required.
Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other, as it may increase the toxicity, mainly gastro-intestinal, even with low doses of acetylsalicylic

acid. 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.
The concurrent administration of corticoids may increase toxicity of the two products and increase the risk of gastro-intestinal ulceration. It should therefore be avoided.
Flunixin may reduce the effect of some anti-hypertensive medicinal product by inhibition of the prostaglandins synthesis, such as diuretics, Angiotensin Conversion Enzyme (ACE) inhibitors and beta blockers.
Concurrent administration of potentially nephrotoxic drugs, particularly aminoglycosides, should be avoided.
Flunixin may reduce renal elimination of some drugs and increase their toxicity (for example, aminoglycosides).

Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

**USER WARNINGS:**

- 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.
- **To avoid possible sensitisation reactions, avoid contact with the skin. 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. In the case of accidental contact with eyes, rinse immediately with plenty of water and seek medical advice.
- Avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
- 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 LEAFLET WAS LAST APPROVED

July 2023

## 15. OTHER INFORMATION

This product is available in cartons containing 1 vial; supplied in 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.

**DISTRIBUTED BY:**

Norbrook Laboratories Limited
Carnbane Industrial Estate
Newry
Co. Down
BT35 6QQ
Northern Ireland

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

Flunixin is toxic to avian scavengers although foreseen low exposure leads to low risk.

BN:
D.O.M:
Exp:

ManA 2000
Vm 02000/4253

To be supplied only on veterinary prescription

**FOR ANIMAL TREATMENT ONLY**
**UK AUTHORISED VETERINARY MEDICINAL PRODUCT**

LOGO

Approved 6 July 2023