PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cronyxin 50 mg/g Oral paste for horses

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Flunixin (as flunixin meglumine) 50 mg/g

3. PACKAGE SIZE

1 x 33 g
2 x 33 g
3 x 33 g
6 x 33 g
12 x 33 g

4. TARGET SPECIES

Horses

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

Meat and offal: 15 days
Milk: Not authorised for use in animals producing milk for human consumption.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 3 months.
Once opened, use by: _____.

9. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

14. MARKETING AUTHORISATION NUMBERS

Vm 50146/5004

15. BATCH NUMBER

Lot: {number}

16. SPECIAL WARNING(S), IF NECESSARY

This product may be harmful to the user. Read the package leaflet before use.

17. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V (‘To be supplied only on veterinary prescription’)

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cronyxin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Flunixin (as flunixin meglumine) 50 mg/g

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP: {month/year}
Once opened use within 3 months
Once opened, use by _____

5. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1 x 33 g
2 x 33 g
3 x 33 g
6 x 33 g
12 x 33 g

6. ROUTE(S) OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIOD

Meat and offal: 15 days
Milk: Not authorised for use in animals producing milk for human consumption.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cronyxin 50 mg/g Oral paste for horses

2. COMPOSITION

1 g of paste contains:

Active substance:

Flunixin	50 mg
(as Flunixin meglumine	83 mg)

White to off-white paste.

3. TARGET SPECIES

Horses

4. INDICATIONS FOR USE

Treatment of acute inflammatory musculoskeletal disorders in horses.

5. CONTRAINDICATIONS

Do not exceed the stated dose or duration of treatment.
Do not administer other NSAIDs or glucocorticosteroids concurrently or within 24 hours of each other.
Do not use in animals suffering from cardiac, hepatic or renal disease.
Do not use in animals suspected of having gastrointestinal ulceration or bleeding.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in dehydrated or hypovolaemic animals, except in the case of endotoxaemia or septic shock, as there is a potential risk of increased renal toxicity.
Do not use in animals suffering from chronic musculoskeletal disorders.

6. SPECIAL WARNING(S)

Use of the veterinary medicinal product may lead to temporary relief due to its ameliorating effects on inflammatory signs. This may appear as effective treatment of the underlying disease. The cause of the underlying inflammatory condition should be determined and treated with appropriate concomitant therapy.

Special precautions for safe use in the target species:

Animals should be rested and an adequate supply of drinking water must be made available during the course of treatment.

Use of any animal less than 6 weeks of age or in aged animals may involve additional risk.

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

This product may cause serious adverse effects when ingested, particularly by children. Keep the product stored in a closed cabinet.

This product may cause hypersensitivity (allergic) reactions. Avoid skin contact with this product.

Wear gloves during application. If you have known hypersensitivity reactions to non-steroidal anti-inflammatory drugs (NSAIDs), do not handle the product. In case of accidental contact with the skin wash exposed area immediately with plenty of water and soap. Hypersensitivity reactions may be serious. If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the physician this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.

This product can cause eye-irritation. Avoid contact with the eyes. If the product comes into contact with the eyes, rinse immediately with plenty of water and seek medical advice.

Pregnancy and lactation:

Do not administer to pregnant mares. Safety studies in pregnant mares have not been conducted.

Interaction with other medicinal products and other forms of interaction:

Concurrent administration of other drugs that may affect the kidneys, particularly aminoglycosides, should be avoided.

The active component of this product may be highly bound to proteins in the blood and therefore should not be given concurrently with other medicinal products that have the same property as this can result in an increase in active concentrations of either or both drugs, leading to toxic effects.

Prior or concurrent administration of steroidal or other non-steroidal anti-inflammatory drugs is not recommended since they may enhance adverse reactions.

Do not use concurrently with the inhalation anesthetic called methoxyflurane because of the potential risk of kidney damage.

Flunixin may reduce the effect of some blood pressure medications, such as diuretics, angiotensin conversion enzyme (ACE) inhibitors, and beta blockers, by inhibition of prostaglandin synthesis.

Overdose:

In case of overdosage, poisoning symptoms such as gastrointestinal disturbances and the effects listed under adverse reactions can occur. In this case, the drug should be discontinued immediately and the animals treated symptomatically.

Major incompatibilities:

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

7. ADVERSE EVENTS

Horses

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Allergic skin reaction Anaphylaxis
Undetermined frequency:
Renal disorder* Digestive tract disorder*

*As for all non-steroidal anti-inflammatory drugs, flunixin may damage the gastrointestinal mucosa and may cause renal damage particularly in hypovolemic and hypotensive conditions, e.g. during surgery.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system http://www.gov.uk/report-veterinary-medicine-problem.

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

Oral use.

1.1 mg flunixin per kg bodyweight once daily for a maximum of 5 days according to clinical response.

Each syringe delivers 1650 mg of flunixin, sufficient to treat 1500 kg bodyweight corresponding to a three days treatment for a 500 kg horse. The syringe is calibrated in 100 kg increments to facilitate dosing of horses of different weights.

9. ADVICE ON CORRECT ADMINISTRATION

Make sure the horse's mouth contains no feed. Insert the syringe into the horse's mouth at the interdental space (between incisor and cheek teeth). Advance the plunger as far as it will go, depositing the medication on the base of the tongue.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 15 days.
Milk: Not authorised for use in animals producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and box after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 3 months.

Once the immediate package is opened, using the shelf-life after first opening, calculate the discard date and record in the space provided.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50146/5004

Pack sizes:
Cardboard box with 1 oral syringe of 33 g.
Cardboard box with 2 oral syringes of 33 g.
Cardboard box with 3 oral syringes of 33 g.
Cardboard box with 6 oral syringes of 33 g.
Cardboard box with 12 oral syringes of 33 g.

Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

March 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

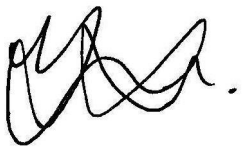
16. CONTACT DETAILS

Name and address of the marketing authorisation holder and of the manufacturing authorisation holder responsible for batch release, if different

Bimeda Animal Health Limited
2/3/4 Airton Close
Tallaght
Dublin 24
Ireland

17. OTHER INFORMATION

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



Approved: 13 May 2024