

CRONYXIN PASTE

50 mg/g Oral Paste for Horses

DATA SHEET



INDICATIONS:

Flunixin 50 mg per gram oral paste, for the treatment of acute inflammatory musculoskeletal disorders in horses.

BENEFITS

- Non-steroidal, non-narcotic analgesic with anti-inflammatory, anti-endotoxic and anti-pyretic activities
- Apple flavour
- Each syringe delivers sufficient to treat 1500kg bodyweight, corresponding to a three day treatment course for a 500kg horse
- 15 day withdrawal period for animals intended for human consumption

PRODUCT CODE	PACK SIZE	CASE SIZE
1CR0047	1 x 33 gram syringe	1 x 10 syringes



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CRONYXIN

50 mg/g Oral Paste for Horses



PRESENTATION

A white to off white oral paste containing 50mg/g of flunixin (as 83mg/g flunixin meglumine).

TARGET SPECIES

Horses

INDICATIONS

Treatment of acute inflammatory musculoskeletal disorders in horses.

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 case 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.

SPECIAL WARNINGS FOR EACH TARGET SPECIES

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 USE IN ANIMALS

Animals should be rested and a sufficient supply of drinking water be provided during the course of treatment with the product.

Use in 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 PRODUCT

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.

ADVERSE REACTIONS

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. In very rare cases (less than 1 animal in 10,000 animals treated; including isolated reports), allergic reactions (allergic skin reactions, anaphylaxis) may occur after administration of the product.

USE DURING PREGNANCY OR LACTATION

Do not use in pregnant mares since reproductive studies have not been conducted.

INTERACTIONS

Concurrent administration of potentially nephrotoxic drugs, particularly aminoglycosides, should be avoided. Some NSAIDs may be highly bound to plasma proteins and may compete with other highly bound drugs to produce an increase in non-bound pharmacologically active concentrations which can lead 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 methoxyfluran because of the potential risk of nephrotoxicity.

Flunixin may reduce the effect of some anti-hypertensive medicinal products, such as diuretics, angiotensin conversion enzyme (ACE) inhibitors, and beta blockers, by inhibition of prostaglandin synthesis.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

For oral administration only.

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

Each syringe delivers 1,650 mg of flunixin, sufficient to treat 1,500 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.

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

OVERDOSE

In case of overdose, signs of toxicity such as gastrointestinal disorders and adverse reactions as listed above can occur. In this case, the drug should be discontinued immediately and the animals treated symptomatically.

WITHDRAWAL PERIOD

Meat and offal: 15 days.

Not authorised for use in animals producing milk for human consumption.

PHARMACODYNAMIC PROPERTIES

Flunixin meglumine is a potent non-steroidal, non-narcotic analgesic with anti-inflammatory, anti-endotoxic and anti-pyretic activities. It acts as a reversible non-selective inhibitor of the enzyme cyclo-oxygenase (both COX-1 and COX-2 forms) reducing the synthesis of eicosanoids involved in tissue inflammation, central pyresis and pain. Flunixin also inhibits the production of thromboxane, a potent

platelet pro-aggregator and vasoconstrictor which is released during blood clotting.

Although flunixin has no direct effect on endotoxins, it reduces prostaglandin production and hence the effects of the prostaglandin cascade that is part of the complex processes involved in the development of endotoxic shock.

PHARMACOKINETIC PARTICULARS

After oral administration of the product to horses at a dose of 1.1 mg flunixin / kg body weight maximal plasma concentrations of 4.7 (\pm 1.1) μ g/ml were reached after approximately 1.5 hours. The AUC₀₋₁₂ of flunixin was 26.2 (\pm 5.2) μ g.hr/ml and elimination took place with a half-life of around 6 hours.

Compared to intravenous administration, a bioavailability of approximately 80 % is achieved. Flunixin strongly binds to proteins and accumulates in the inflammatory exudate, resulting in delayed elimination.

ENVIRONMENTAL PROPERTIES

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

LIST OF EXCIPIENTS

Silica, colloidal anhydrous
Propylene glycol
Titanium dioxide
Xanthan gum
Aluminium Magnesium Silicate
Sorbitol
Apple flavour
Purified water

MAJOR INCOMPATIBILITIES

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

SHELF LIFE

Shelf life of the product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging: 3 months.

STORAGE

This product does not require any special storage conditions.

DISPOSAL

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

LEGAL CATEGORY

POM - V

MARKETING AUTHORISATION NUMBER

GB: Vm 50146/5004

NI: Vm 50146/3003

MARKETED IN THE UK BY

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TAKE TIME



OBSERVE LABEL DIRECTIONS

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