CRONYXIN

50 MG/G ORAL PASTE FOR HORSES

DATA SHEET

INDICATIONS:

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
- Flexible dose syringe
- Each syringe delivers sufficient to treat 1500kg bodyweight, corresponding to a three-day treatment course for a 500kg horse

PRODUCT CODE	PACK SIZE	CASE SIZE
1CRO045	1 x 33 gram syringe	1 x 10 syringes

See reverse for Administration & Dosage

CRONYXIN

50 mg/g Oral paste for horses

ACTIVE SUBSTANCE
1 gram of paste contains flunixin 50.0 mg (as flunixin meglumine) 83.0 mg
Oral white to off-white paste in a syringe barrel and dial-a-dose plunger with cap, containing 33 grams of paste. The plunger is graduated to give set doses corresponding to 100 kg bodyweight per graduation.

TARGET SPECIES
Horses

INDICATIONS FOR USE
Treatment of acute inflammatory musculoskeletal disorders in horses

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 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.
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.

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

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 has to be ensured during the course of treatment with the veterinary medicinal product.
Use in any animal less than 6 weeks of age or in aged animals may involve additional risk.

Special precautions to be taken by the person administering the veterinary medicinal 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, e.g. during surgery. In very rare cases allergic reactions (allergic skin reactions, anaphylaxis) may occur after administration of the veterinary medicinal product.

USE DURING PREGNANCY OR LACTATION
Do not use in pregnant mares since reproductive studies have not been conducted in horses.

INTERACTION WITH OTHER MEDICINAL PRODUCTS
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.

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

PHARMACODYNAMIC PROPERTIES
Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, non-steroids, flunixin.
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 veterinary medicinal product to horses at a dose of 1.1 mg flunixin / kg body weight maximal plasma concentrations of 4.7 (± 1.1) µg/ml were reached after approximately 1.5 hours. The AUCi of flunixin was 26.2 (± 5.2) µg.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.

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

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

SPECIAL PRECAUTIONS FOR STORAGE
This veterinary medicinal product does not require any special storage conditions.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

MARKETING AUTHORISATION HOLDER
Bimeda Animal Health Limited
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MARKETING AUTHORISATION NUMBER
VPA22033/034/001

LEGAL CATEGORY
POM

TAKE TIME OBSERVE LABEL DIRECTIONS

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