[Version 9,03/2022] corr. 11/2022

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cronyxin 50 mg/g Oral paste for horses (DE, AT, BE, EE, ES, FR, IE, IT, NL, PL, UK(NI))
Cronyxin vet 50 mg/g Oral paste for horses (SE)
Cronyxin vet (DK)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of paste contains:

Active substance:

Flunixin	50 mg
(as Flunixin meglumine	83 mg)

Excipients:

Qualitative composition of excipients and other constituents
Silica, colloidal anhydrous
Propylene glycol
Titanium dioxide (E171)
Xanthan gum
Aluminium magnesium silicate
Sorbitol, liquid (crystallising)
Apple flavour FL02791
Purified water

White to off-white paste

3. CLINICAL INFORMATION

3.1 Target species

Horses

3.2 Indications for use for each target species

Treatment of acute inflammatory musculoskeletal disorders in horses.

3.3 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.

See also section 3.7.

3.4 Special warnings

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.

3.5 Special precautions for use

Special precautions for safe use in the target species
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.
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.

Special precautions for the protection of the environment:
Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

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.

3.9 Administration routes and dosage

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.
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.

3.10 Symptoms of overdose (and where applicable, emergency procedures, antidotes)

In case of overdosage, signs of toxicity such as gastrointestinal disorders and adverse reactions listed in section 3.6 can occur. In this case, the drug should be discontinued immediately and the animals treated symptomatically.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

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

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QM01AG90

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 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.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

White high-density polyethylene syringe barrel and dial-a-dose plunger with low-density polyethylene cap, containing 33 grams of paste. The plunger is graduated to give set doses corresponding to 100 kg bodyweight per graduation. See also section 3.9.

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.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Ltd.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}.

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}.

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database *(https://medicines.health.europa.eu/veterinary)*.