Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Cronyxin Injection 50 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Flunixin (as Flunixin Meglumine) 50.0 mg

Excipients:
Phenol Ph.Eur. 5.0 mg
Sodium formaldehyde sulfoxylate 2.2 mg

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection
Clear, colourless to light yellow solution, free of foreign matter

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle and horses.

4.2 Indications for use, specifying the target species

Cattle: For the control of acute inflammation associated with respiratory disease. Cronyxin Injection may be used as adjunctive therapy in the treatment of acute mastitis.

Horses: For the alleviation of inflammation and pain associated with musculoskeletal disorders. It is also indicated for the alleviation of visceral pain associated with colic.

4.3 Contraindications

Do not use 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 or hypersensitivity to the product.

4.4 Special warnings for each target species

Avoid use in dehydrated, hypovolaemic or hypotensive animals, as there is a potential risk of increased renal toxicity.

4.5 Special precautions for use

Special precautions for use in animals

NSAIDs can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be instigated.

Avoid intra-arterial injection.

Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs to produce an increase in non-bound pharmacologically active concentrations, which can lead to toxic effects.

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 careful clinical management.

It is preferable that flunixin is not administered to animals undergoing general anaesthesia until fully recovered.

Avoid concurrent administration of potentially nephrotoxic drugs.

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

None.

4.6 Adverse reactions (frequency and seriousness)

Prolonged use of NSAIDs, including flunixin, may predispose or lead to gastrointestinal irritation, and in severe cases, ulceration.

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant mares. Studies to demonstrate safety in pregnant mares have not been conducted

4.8 Interaction with other medicinal products and other forms of interactions

Do not administer other NSAIDs concurrently or within 24 hours of each other. Due to their common mode of action, flunixin may potentiate and be potentiated by other NSAIDs which act by interfering with prostaglandin synthesis.

Cronyxin Injection may potentiate the effects of warfarin and other drugs.

Monitor drug compatability closely where adjunctive therapy is required.

Do not mix Cronyxin Injection with other medicaments prior to administration.

4.9 Amounts to be administered and administration route

Cattle: The recommended dose is 2 ml Cronyxin Injection per 45 kg bodyweight (equivalent to 2.2 mg flunixin per kg) injected intravenously and repeated as necessary at 24 hour intervals for up to 5 consecutive days. The cause of the acute inflammatory condition should be determined and treated with concomitant therapy.

Horses: For use in equine musculoskeletal disorders, the recommended dose is 1 ml of Cronyxin Injection per 45 kg bodyweight (equivalent to 1.1 mg flunixin per kg bodyweight) injected intravenously once daily for up to 5 days according to clinical response.

For equine colic disorders the recommended dose is 1 ml of Cronyxin Injection per 45 kg bodyweight (equivalent to 1.1 mg flunixin per kg bodyweight) injected intravenously, repeated once or twice if colic recurs. The cause of colic should be determined and treated with concomitant therapy.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Do not exceed the recommended dose or treat animals for more than 5 consecutive days.

4.11 Withdrawal period(s)

Milk from lactating cows should be discarded during treatment and may only be taken for human consumption after 36 hours following treatment. Animals may not be slaughtered for human consumption during treatment. Animals may be slaughtered for human consumption only after 7 days from the last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Cronyxin Injection is a multidose parenteral product containing flunixin (as flunixin meglumine) 50 mg per ml.

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

It acts by interfering with the arachidonic acid pathway of prostaglandin synthesis.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Phenol
Disodium Edetate
Sodium formaldehyde sulfoxylate
Sodium Hydroxide (for pH adjustment)
Hydrochloric Acid (forpH adjustment)
Water for Injection

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first broaching the vial: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

50 ml and 100 ml clear, Type I glass, multidose vials, with bromobutyl rubber bung and aluminum overseal.

Not all pack sizes may be marketed.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Airton Road
Tallaght
Dublin 24
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8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/040/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20 February 1996
Date of last renewal: 20 February 2006

10 DATE OF REVISION OF THE TEXT

August 2020