SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cronyxin Injection, 5% w/v Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance(s):	mg
Flunixin	50
(as Flunixin Meglumine)	

Excipient(s):	
Phenol (as preservative)	5
Sodium Formaldehyde Sulfoxylate (as antioxidant)	2.2

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. It has also been shown to have some benefit in the treatment of experimental acute bovine pulmonary emphysema (Fog fever).

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 Contra-indications

Do not exceed the stated dose or duration of treatment.

Use is contra-indicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, where this is evidence of blood dyscrasia or hypersensitivity to the product.

Do not administer other NSAIDs concurrently or within 24 hours of each other.

Avoid intra-arterial injection.

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

4.4 Special warnings for each target species

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.

4.5 Special Precautions for use

i. Special precautions for use in animals

Administer by slow intravenous injection.

Do not mix Cronyxin with other medicaments prior to administration.

Do not administer to racehorses within 8 days of racing.

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 a reduced dosage and careful clinical management.

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

Concurrent administration of potentially nephrotoxic drugs should be avoided.

ii. Special safety precautions to be taken by the person administering the veterinary product to animals

Avoid eye contact and direct contact with skin.
To avoid possible sensitisation reactions, avoid contact with skin. Gloves should be worn during application.
Wash hands after use.
In the case of accidental contact with eyes, rinse immediately with plenty of water and seek medical advice.
The product may cause reactions in sensitive individuals. If you have known hypersensitivity to non-steroidal anti-inflammatory products, do not handle the product. Reactions may be serious.
Avoid self-injection.

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 and lactation

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

4.8 Interaction with other medicaments and other forms of interactions

Monitor drug compatibility closely where adjunctive therapy is required. Cronyxin may potentiate the effects of warfarin and other drugs.

Due to their common mode of action, flunixin may potentiate and be potentiated by other NSAIDs, which act by interfering with prostaglandin synthesis.

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 acute inflammatory conditions should be determined and treated with concomitant therapy.

Horses For use in equine musculoskeletal disorders, the recommended dose is 1 ml Cronyxin Injection per 45 kg bodyweight (equivalent to 1.1 mg flunixin per kg) injected intravenously and repeated as necessary at 24 hour intervals for up to 5 consecutive days according to clinical response.

For use in equine colic, the recommended dose is 1 ml Cronyxin Injection per 45 kg bodyweight (equivalent to 1.1 mg flunixin per kg) injected intravenously and repeated once or twice if signs of colic recur. 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. Tolerance trials in cattle and horses confirmed excellent tolerance to Cronyxin at twice the recommended dose.

4.11 Withdrawal Periods

Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

Cattle may be slaughtered for human consumption only after 8 days from the last treatment.

Milk from lactating cows should be discarded during treatment. Milk for cows should only be taken for human consumption from 12 hours following cessation of treatment.

5. PHARMACOLOGICAL PROPERTIES

Pharmaceutical group: Fenamate - Flunixin
ATCvet code: QM01AG90

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

Phenol
Sodium Formaldehyde Sulfoxylate
Disodium Edetate Dihydrate
Propylene Glycol
Sodium Hydroxide (for pH adjustment)

Hydrochloric acid (for pH adjustment)
Water for injections

6.2 Incompatibilities

None known

6.3 Shelf Life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf-life after opening the immediate packaging: 28 days.

6.4 Special Precautions for Storage

Following withdrawal of the first dose, use the product within 28 days.
Do not store above 25°C.

6.5 Nature and composition of immediate packaging

50 ml & 100 ml clear glass Type I Vial with rubber bromobutyl bung with aluminium overseal.

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

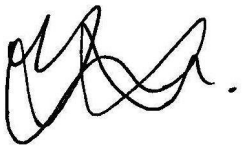
Vm 50146/4011

9. DATE OF FIRST AUTHORISATION

14 March 1996

10. DATE OF REVISION OF THE TEXT

June 2020



Approved: 29 June 2020