[Version 9,03/2022]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Cronyxin Injection 50 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:

Flunixin (as Flunixin Meglumine) 50.0 mg/ml

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Propylene glycol	
Phenol	5.0 mg/ml
Disodium edetate	
Sodium formaldehyde sulfoxylate	2.2 mg/ml
Sodium hydroxide (for pH adjustment)	
Hydrochloric acid (for pH adjustment)	
Water for injection	

Clear, colourless to light yellow solution, free of foreign matter.

3. CLINICAL INFORMATION

3.1 Target species

Cattle
Horses

3.2 Indications for use for each target species

Cattle: For the control of acute inflammation associated with respiratory disease. The veterinary medicinal product may be used as adjunctive therapy in the treatment of acute mastitis.

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

3.3 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 veterinary medicinal product.

3.4 Special warnings

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

3.5 Special precautions for use

Special precautions for safe use in the 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.
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.
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:
Not applicable.

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

3.6 Adverse events

Horses and Cattle:

Undetermined frequency (Cannot be estimated from the available data):	Gastrointestinal irritation[1] Gastrointestinal ulceration[2]

[1]Prolonged use of NSAIDs, including flunixin
[2]Prolonged use of NSAIDs, including flunixin, in severe cases

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 the last section of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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

3.8 Interaction with other medicinal products and other forms of interaction

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.
The veterinary medicinal product may potentiate the effects of warfarin and other drugs.
Monitor drug compatibility closely where adjunctive therapy is required.
Do not mix the veterinary medicinal product with other medicaments prior to administration.

3.9 Administration routes and dosage

Cattle:
The recommended dose is 2 ml of veterinary medicinal product 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 veterinary medicinal product 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 veterinary medicinal product 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.

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

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

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:
Cattle: 7 days
Horses: 7 days

Milk:
Cattle: 36 hours
Horses: Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QM01AG90

4.2 Pharmacodynamics

The veterinary medicinal product is a multidose parenteral product containing flunixin (as flunixin meglumine) 50 mg/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.

Environmental properties

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

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: 28 days

5.3 Special precautions for storage

Do not store above 25°C.

5.4 Nature and composition of immediate packaging

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

7. MARKETING AUTHORISATION NUMBER(S)

VPA 22033/040/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 20 February 1996

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

12/2022

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).