PART III

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the Veterinary Medicinal Product

Cronyxin Injection

2. Qualitative and Quantitative Composition

Each ml contains:

Active Substance	per ml	
Flunixin (as Flunixin Meglumine)	50 mg	
Excipients		**Function**
Phenol Ph.Eur.	5 mg	Preservative
Sodium formaldehyde sulfoxylate	2.2 mg	Antioxidant

3. Pharmaceutical Form

Solution for injection.

4. Pharmacological 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.

5. CLINICAL PARTICULARS

5.1 Target Species

Cattle and horses.

5.2 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.

5.3 Contra-indications

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.

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

5.4 Undesirable Effects (Frequency and Seriousness)

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

5.5 Special precautions for use

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.

Concurrent administration of potentially nephrotoxic drugs should be avoided.

5.6 Use During Pregnancy and Lactation

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

5.7 Interaction with other Medicaments and other Forms of Interaction

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

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.

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

5.8 Posology and Method of Administration

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 1ml Cronyxin Injection per 45kg bodyweight (equivalent to 1.1mg 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.

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

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

5.10 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.

Avoid intra-arterial injection.

5.11 Withdrawal Periods

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.

5.12 Special Precautions to be taken by the Person Administering the Product to Animals

None.

6. PHARMACEUTICAL PARTICULARS

6.1 Incompatibilities

None known.

6.2 Shelf-life

Unopened
A shelf life expiry date of 2 years is recommended for the product.

Broached
Discard any unused solution after 28 days.

6.3 Special Precautions for Storage

Do not store above 25°C.

6.4 Nature and Contents of Container

50 ml and 100 ml clear, Type II glass, multidose vials, with bromobutyl rubber bung containing a clear colourless liquid.

6.5 Special Precautions for the Disposal of Unused Medicinal Product or Waste Materials, if any

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

7. Name or Corporate Name and Address or Registered Place of Business of the Authorisation Holder

Bimeda Chemicals Ltd.,
Broomhill Road,
Tallaght,
Dublin 24.

8. FINAL INFORMATION

8.1 Marketing Authorisation Number

VPA 10126/64/1

8.2.1 Date of Approval of SPC

20th February 2001

8.2.2 Date of Revision of SPC

28th March 2003