Veterinary Medicine

For Animal Use Only

SCHEDULING STATUS S3

PROPRIETARY NAME AND DOSAGE FORM
Pyroflam NS Injection.

COMPOSITION
Each 1,0 mℓ solution contains:
Flunixin (as flunixin meglumine) 50,0 mg

Preservative: Phenol 0,5 % *m/v*.

PHARMACOLOGICAL CLASSIFICATION
C 1.8 Analgesic antipyretics.

PHARMACOLOGICAL ACTION
Flunixin meglumine is a non-narcotic, non-steroidal analgesic with anti-inflammatory, anti-endotoxic and antipyretic properties.
Flunixin meglumine acts as a reversible inhibitor of cyclo-oxygenase an important enzyme in the arachidonic acid cascade which is responsible for converting arachidonic acid to cyclic endoperoxides. Consequently, synthesis of eicosanoids, important mediators of the inflammatory process involved in central pyresis, pain perception and tissue inflammation is inhibited. Through its effects on the arachidonic acid cascade, flunixin also inhibits the production of thromboxane, a platelet pro-aggregator and vasoconstrictor which is released during blood clotting.
Flunixin exerts its antipyretic effect by inhibiting prostaglandin E_2 synthesis in the hypothalamus. By inhibiting the arachidonic acid cascade, flunixin also produces an anti-endotoxic effect by suppressing eicosanoid formation and therefore preventing their involvement in endotoxin disease states.

INDICATIONS
Horses: Pyroflam NS is indicated for the alleviation of inflammation and pain associated with musculoskeletal disorders and for the alleviation of visceral pain associated with colic.
Cattle: Pyroflam NS is indicated for the control of acute inflammation associated with respiratory disease.

CONTRAINDICATIONS
Do not administer to pregnant mares and to foals younger than 72 hours. Use is contraindicated in animals suffering from cardiac, hepatic, or renal disease, where there is a possibility of gastrointestinal ulceration or bleeding, where there is evidence of a blood dyscrasia or hypersensitivity to the product.

WARNINGS AND SPECIAL PRECAUTIONS
Animals must not be slaughtered for human consumption within 10 days after administration.
Milk for human consumption may only be taken from treated cows 24 hours after administration of Pyroflam NS. Avoid intra-arterial injection.
Do not use in cats.
Young animals (less than 30 days of age) are more susceptible to toxicity due to a deficiency in the enzyme glucoronyl transferase, an important conjugation mechanism.
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 dose and careful clinical management.
Avoid use in any dehydrated, hypovolaemic or hypotensive animal. It is preferable that flunixin is not administered to animals undergoing general anaesthesia until fully recovered.

INTERACTIONS
Monitor medicine compatibility closely where adjunctive therapy is required. Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound medicines which can lead to toxic effects. Concurrent administration of potentially nephrotoxic medicines should be avoided.

DOSAGE AND DIRECTIONS FOR USE
Pyroflam NS is indicated for intravenous administration to cattle or horses.
Do not mix Pyroflam NS with other medication prior to administration.
Do not exceed the recommended dose or the duration of treatment.
Following withdrawal of the first dose from the vial, use the product within 28 days.
Discard unused product.

Horses:
For the use in colic the recommended dose rate is 1,1 mg flunixin / kg bodyweight equivalent to 1 mℓ per 45 kg bodyweight. Treatment may be repeated once or twice if colic recurs.
For use in musculoskeletal disorders, the recommended dose rate is 1,1 mg flunixin / kg bodyweight equivalent to 1 mℓ per 45 kg, once daily for up to 5 days according to clinical response.

Cattle:
The recommended dose rate is 2,2 mg flunixin / kg bodyweight equivalent to 2 mℓ per 45 kg bodyweight. Repeat as necessary at 24-hour intervals for up to 5 consecutive days. The cause of the underlying inflammatory condition or colic should be determined and receive appropriate concomitant therapy.

SIDE EFFECTS
Untoward effects include gastrointestinal ulceration and, in dehydrated or hypovolaemic animals, potential for renal damage. Prolonged use, or higher than recommended dose rates, may lead to a life-threatening plasma protein enteropathy due to gastrointestinal ulceration.
Nephrotoxicity in the form of papillary necrosis, bone-marrow suppression resulting in blood dyscrasias and impaired hepatic function may occur.
Intra-arterial administration of flunixin may result in ataxia, rapid breathing, muscle weakness and central nervous system effects.
Isolated reports of local reactions following intramuscular injection in the horse, particularly in the neck have been reported. These include sweating, swelling, induration and stiffness.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT
See "Side effects".

IDENTIFICATION
A clear, colourless solution free of visible particles.

PRESENTATION
Pyroflam NS is supplied in 50 mℓ, 100 mℓ and 250 mℓ clear glass vials.

STORAGE INSTRUCTIONS
Store at or below 25 °C. Protect from light. Keep out of reach of children, uninformed persons and animals.

REGISTRATION NUMBER
99/2.6/4

EXPORT COUNTRIES:
Botswana: POM BV2400762/A/B
Namibia: NS2 V06/2.6/1172

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION
KYRON ANIMAL HEALTH (PTY) LTD
Reg. No.2004/021847/07
Unit 45A, 45 Parkview Street
Highway Business Park
Roohuiskraal, Extension 31
Centurion, South Africa.
Tel: 010-880 0778

KYRON

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