FLUNICURE 50MG/ML INJECTION

Description and Composition
FLUNICURE 50MG/ML INJECTION is a colourless to light clear solution. Each ml contains 50mg Flunixin (as meglumine) as its active ingredient and 5mg Phenol as preservative.

Pharmacodynamics
Flunixin meglumine is a relatively potent non-narcotic, non-steroidal analgesic with anti-inflammatory, anti-endotoxic and anti-pyretic properties.
Flunixin meglumine acts as a reversible inhibitor of cyclo-oxygenase, an important enzyme in the arachidonic acid cascade pathway 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 potent platelet pro-aggregator and vasoconstrictor which is released during blood clotting. Flunixin exerts its antipyretic effect by inhibiting prostaglandin E2 synthesis in the hypothalamus. By inhibiting the arachidonic acid cascade pathway, flunixin also produces an anti-endotoxic effect by suppressing eicosanoid formation and therefore preventing their involvement in endotoxin associated disease states.

Pharmacokinetics
Flunixin was administered intravenously to horses as a single dose of 1.1mg/kg. At the first timepoint measured (10 minutes after administration) the plasma concentration was 11.45µg/ml, AUC was 21.45µg.h/ml and the elimination half-life was approximately 2 hours.
Flunixin was administered intravenously to cattle as a single dose of 2.2mg/kg. At the first timepoint measured (10 minutes after administration) the plasma concentration was 12.32µg/ml, AUC was 14.87µg.h/ml and the elimination half-life was approximately 4 hours.
In an experimental study, flunixin was administered intravenously to pigs as a single dose of 2.0mg/kg. Flunixin was >98% protein bound at all physiologically relevant concentrations, but also had a large volume of distribution at steady-state. All plasma concentrations were below the limit of quantitation (0.02µg/ml) by 48 hours and the elimination half-life was 7.76 hours.

Indication
Cattle: For the control of acute inflammation associated with respiratory disease. For the treatment of acute bovine pulmonary emphysema (Fog Fever). For use as an adjunctive therapy in the treatment of acute mastitis.

Horses: For the alleviation of inflammation and pain associated with musculo-skeletal disorders. For the alleviation of visceral pain associated with colic in the horse.

Pigs: For use as an adjunctive therapy in the treatment of swine respiratory diseases.

Recommended Dose
Cattle: 2ml per 45kg body weight (equivalent to 2.2mg Flunixin per kg) administered intravenously. Repeat as necessary at 24 hour intervals for up to 5 consecutive days.

Horses:
By intravenous injection for musculo-skeletal disorders:
1ml per 45kg body weight (1.1mg Flunixin per kg) once daily for up to 5 days according to clinical response.
By intravenous injection for colic:
1ml per 45kg body weight (1.1mg Flunixin per kg) repeated once or twice if colic recurs.
For the treatment of endotoxaemia or septic shock associated with gastric torsion and with other conditions in which the circulation of blood to the gastro-intestinal tract is compromised: 0.25mg per kg every 6 to 8 hours, by intravenous injection.

Pigs: 2ml per 45 kg body weight (equivalent to 2.2mg Flunixin per kg) once by intramuscular injection, in the neck, in conjunction with appropriate antimicrobial therapy. The injection volume should be limited to a maximum of 5 ml per injection site.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes. When intramuscular injection is used, the dose should be divided between two injection sites on either side of the neck..

Route of Administration
Cattle and horses: By intravenous (IV)
Pigs: By intramuscular (IM)

Contraindication
Do not exceed the stated dose or the 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, or where there is hypersensitivity to the product.
Do not use the product within 48 hours before expected parturition in cows.
Do not administer to pregnant mares.
Do not administer to pregnant sows, gilts at mating and in breeding boars.

Warning and Precautions
Special warning for target species:
Non-steroidal, anti-inflammatory drugs are not permitted under the rules of Racing and under rules covering other competitive events. The Royal College of Veterinary Surgeons has given advice to the Veterinary Profession regarding the use of anti-inflammatory drugs in competing horses. It states that "if a veterinarian recommends the discontinuation of any such drug not less than eight days before racing, he should feel sure that he has catered for all but the most exceptional case". Do not exceed the recommended dose or duration of treatment.

Special precautions for use:
i. Special precautions for use in animals
Avoid intra-arterial injection.
NSAIDS are known to have the potential to delay parturition through a tocolytic effect by inhibiting prostaglandins that are important in signalling the initiation of parturition. The use of the product in the immediate post-partum period may interfere with uterine involution and expulsion of foetal membranes resulting in retained placentae. See also section Pregnancy and Lactation.
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.
Do not use in hypovolaemic animals except in the case of endotoxaemia or septic shock.
It is preferable that NSAIDs which inhibit prostaglandin synthesis are not administered to animals undergoing general anaesthesia until fully recovered.
The cause of colic should be determined and treated with concurrent therapy.
The product should not be used in piglets weighing less than 6 kg.

ii. Special precautions to be taken by the person administering the veterinary medicinal product to animals
Avoid contact with skin or eyes.
In case of skin contact, wash exposed area with water.
In case of eye contact, wash eyes thoroughly with clean water and seek medical advice.
Take care against accidental self-injection.
Wash hands after use.

Interaction with Other Medicinal Product
Do not administer other NSAIDs concurrently or within 24 hours of each other.
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.
Concurrent administration of potentially nephrotoxic drugs should be avoided.

Pregnancy and Lactation
The product may be used in pregnant and lactating cattle.
The product should only be administered within the first 36 hours post-partum following a benefit/risk assessment performed by the responsible veterinarian and treated animals should be monitored for retained placentae.
Do not use in pregnant mares or pregnant sows. Safety studies in pregnant mares and pregnant sows have not been conducted.

Side Effects
Flunixin meglumine is a non-steroidal anti-inflammatory drug (NSAID). Untoward effects include gastro-intestinal irritation, ulceration and, in dehydrated or hypovolaemic animals, potential for renal damage.
In pigs transient irritation may occur at the injection site, this resolves spontaneously within 14 days.

Symptoms and Treatment of Overdose
Overdosage studies in the target species have shown the product to be well-tolerated. Flunixin meglumine is a non-steroidal anti-inflammatory drug. Overdosage is associated with gastrointestinal toxicity. Concurrent use of nephrotoxic drugs should be avoided.

Storage Condition
Store below 30ºC.

Shelf life
3 years. Following withdrawal of the first dose, use the product within 24 hours. Any unused material should be discarded.

Withdrawal Periods
Animals must not be slaughtered for human consumption during treatment.
Cattle: 5 days from the last treatment.
Horses: 7 days from the last treatment.
Pigs: 22 days from the last treatment.
Milk: Milk for human consumption must not be taken during treatment. Milk for human consumption may only be taken from cattle after 24 hours from the last treatment.

Packing
20ml, 50ml, 100ml.

Revision date: 5.12.2019

	Manufacturer & Product Registration Holder:
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