For Veterinary Use Only.

Fulimed®

Solution for Injection

Nonsteroidal Anti-inflammatory-Antirheumatismal Veterinary

COMPOSITION:

Fulimed Solution for Injection is a clear, colourless, odourless, viscous solution containing flunixin meglumine equivalent to 50 mg flunixin per each ml.

PHARMACOLOGICAL PROPERTIES:

Fulimed Solution for Injection is a nonsteroidal anti-inflammatory (NSAID), anti-endotoxic, antipyretic and non-narcotic analgesic drug. It demonstrates its effect by inhibiting the cyclooxygenase enzyme system which catalyzes the transformation of arachidonic acid into Prostaglandin G2 (PGG2). Prostaglandins are responsible for many indications of inflammation alone or in synergy with substances such as bradykinin or histamine.

The pharmacological effect of Fulimed Solution for Injection is based on the elimination of inflammatory effects of PGI2, known as the strongest mediator prostacycline in the acute inflammation, such as vasodilatation, inhibition of the aggregation of blood-platelets, increment of vascular permeability, fever, myalgia, pain in synergy with bradykinin, inhibition of T-cells and increment of the sensitivity of pain receptors. Flunixin reduces many indications regarding endotoxic shock. These indications include the reduction of lactic acidosis, reduction of the extension of coagulation time, reduction of leucopoenia and the reduction of the increment of certain serum enzymes such as creatinine kinase, lactic dehydrogenase and sorbitol dehydrogenase. Following the intravenous administration of a single dose of 1.1mg/kg in horses, Flunixin may be detected for 8 hours and 48 hours in plasma and urine, respectively. The half life is specified in horses and cattle as 1.6 hours and 3.68±0.7 hours, respectively.

AREA OF USE / INDICATIONS:

Fulimed Solution for Injection is used as nonsteroidal anti-inflammatory, anti-endotoxic, antipyretic and non-narcotic analgesic in cattle, horses and dogs.

Cattle : It is used in all types of acute inflammations, infections with fever, endotoxic shock, colibacillosis, pneumonia and for the control of acute inflammations regarding chronic obstructive respiratory diseases, and as a supplement for the treatment of acute cattle pulmonary emphysema (Fog Fever) and acute mastitis.

Horse : It is indicated in the reduction of visceral pain arising from inflammation and locomotor disorders or colic.

In cattle and dogs; it is generally used in the treatment of tendon pain, skeletal muscle system pains, inflammatory states and pains and aches in internal organs caused by smooth muscle aches.

USAGE AND DOSAGE:

Fulimed Solution for Injection is administered intramuscularly and intravenously in cattle and horses. It is administered only intravenously in dogs. The pharmacological dose of Flunixin as per the target animal species is 2.2mg/kg c.a in cattle; 1.1mg/kg c.a in horses and 0.5 - 2 mg/kg c.a in dogs.

Fulimed Solution for Injection;

Cattle : 2 ml/45kg CA

It may be used at intervals of 24 hours or by dividing the daily dose (2.2 mg/kg CA) into two parts and administering it at a dose of 1.1 mg/kg CA 3 times, as two times a day, at an interval of 12 hours.

Horse : 1 ml/45kg CA

In case of skeletal-muscle system disorders, it may be used for 5 days at intervals of 24 hours, if required. In case of colic in horses, it is repeated intravenously (IV) at a dose of 1ml /45kg CA once or two times. It may be administered for maximum 5 days.

It may only be administered to dogs intravenously for 3 days (once in a day) at a dose of 0.5-2mg/kg CA.

SPECIFIC CLINICAL INFORMATION AND SPECIAL WARNINGS FOR TARGET SPECIES:

It may be risky to be administered to animals younger than 6 weeks. If the abovementioned case is required, then it should be used with special care and at lower doses. Pay attention to avoid exceeding the specified treatment dose in horses and cattle. Since it may cause restrictions of liver and kidney functions in older horses, it should be used with special care and at as lower doses as possible. Pony horses have the highest sensitivity for flunixin. This requires controlled administration at a lower dose. Avoid injecting into artery veins in horses and cattle.

Intravenous injections should be performed as slowly as possible. NSAIDs lead to the inhibition of phagocytosis. Therefore, it should be used together with suitable antibiotics for the treatment of bacterial infections.

UNDESIRED/SIDE EFFECTS

High doses or long-term administrations may result in erosion, ulcer and bleedings in the mucosa of gastro-intestinal system. Transient pain may develop in the administration area during intravenous injections in horses. Following intramuscular administration in cattle pain, oedema, inflammation and tissue damage may develop in the administration area. Rarely anaphylaxis and death have been reported to be observed in especially horses against flunixin.

DRUG INTERACTIONS:

Flunixin strengthens the effects of other nonsteroidal anti-inflammatory drugs (NSAID), general anaesthetics, corticosteroids, nephrotoxic drugs and substances as warfarin. Therefore, concurrent administration with these drugs should be avoided.

SYMPTOMS OF OVERDOSE, PRECAUTIONS AND ANTIDOTE:

The recommended therapeutic doses should not be exceeded and long-term administration should be avoided. Following administration of flunixin at a dose of 3 times of the daily dose in horses for 10 days and at the treatment doses in cattle for 9 days, no changes developed in the blood and urine values. It resulted in the rare presence of blood in the excrement and urine upon administration at a dose of 3 and 5 times of the daily dose in cattle for 9 days.

WARNINGS ON DRUG RESIDUES IN FOOD:

Withholding Period (WHP): The meat type animals should not be sent for slaughter before 21 days following the final drug administration and during the treatment. The milk obtained should not be presented for human consumption during drug administration and for 5 days (10 milkings) following drug discontinuation.

CONTRAINDICATIONS:

Avoid administering in animals with renal, hepatic and cardiac disorders. Since it may lead to gastro-intestinal ulcer and bleeding it is contraindicated in animals with blood disorders or hypersensitivity for the product. In horses and cattle, anaphylactic reactions may develop following intravenous (IV) administration of flunixin, even if

rare. In this case, discontinue drug administration and apply symptomatic treatment immediately. Flunixin may increase the effects of other NSAIDs. Therefore, avoid using with other NSAIDs within 24 hours. Fulimed Solution for Injection should not be used in animals under general anaesthesia and before the animal wakes up.
Use during pregnancy: It should be used with special care in pregnant animals despite no side effects have been reported on teratogenicity, breeding performance and pregnancy.

GENERAL WARNINGS:

Consult your veterinary surgeon before using and in case an undesired effect is observed. Keep out of reach of children. Consume the drug within 28 days following the initial administration.

STORAGE CONDITIONS AND SHELF LIFE:

Protect from light. Store at room temperature (15-25℃). Shelf life is 3 years as of the production date .

COMMERCIAL PRESENTATION FORM INDICATING THE QUALITY AND QUANTITY OF THE PACKAGE:

Presented to the market in 20, 50 and 100ml transparent vials in squared box packages.

PLACE AND CONDITIONS OF SALE:

Sold with Veterinary Surgeon's prescription in pharmacies and veterinary surgeries (VSP).

APPROVAL DATE OF PACKAGE INSERT: 06.12.2004

MINISTRY OF AGRICULTURE AND RURAL AFFAIRS MARKETING AUTHORIZATION DATE AND NO: 24.10.2000-10/910

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

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