Flunixin®
(flunixin meglumine)
Injectable Solution
50 mg/mL
Sterile Solution
VETERINARY USE
MULTI-DOSE VIAL
NOT FOR USE IN HUMANS
KEEP OUT OF REACH OF CHILDREN
For Intravenous or Intramuscular Use in Horses and for Intravenous Use in Beef and Dairy Cattle. Not for Use in Dry Dairy Cows and Veal Calves.
CAUTION
Federal law restricts this drug to use by or on the order of a licensed veterinarian.
DESCRIPTION
Each milliliter of FLUNIXAMINE Injectable Solution contains flunixin meglumine equivalent to 50 mg flunixin, 0.1 mg edetate disodium, 2.2 mg sodium formaldehyde sulfonate, 4.0 mg diethylenetriamine, 207.2 mg propylene glycol, 5.0 mg phenol as preservative, hydrochloric acid, water for injection q.s.
PHARMACOLOGY
Flunixin meglumine is a potent, non-narcotic, nonsteroidal, analgesic agent with anti-inflammatory and antipyretic activity. It is significantly more potent than pentazocine, meperidine, and codeine as an analgesic in the rat yeast paw test. Flunixin is four times as potent as a mg-per-mg basis as phenylbutazone as measured by the reduction in lameness and swelling in the horse. Plasma half-life in horse serum is 1.6 hours following a single dose of 1.1 mg/kg. Measurable amounts are detectable in horse plasma at 8 hours postinjection.
Horse:
Flunixin is a weak acid (pKa= 5.82) which exhibits a high degree of plasma protein binding (approximately 99%). However, free (unbound) drug appears to readily partition into body tissues (\( V_d \)). Predictions range from 297 to 782 mL/kg.\(^1\) Total body water is approximately equal to 570 mL/kg.\(^1\) In cattle, elimination occurs primarily through biliary excretion.\(^2\) This may, at least in part, explain the presence of multiple peaks in the blood concentration/time profile following intravenous administration.\(^4\) IV administration produces no changes in blood or urine parameters. No injection site irritation was observed
Horse:
Intravenous use.
Cattle:
Intramuscular administration has resulted in violative residues in the edible tissues of cattle. Intramuscular administration should be avoided.
CONTRAINDICATIONS
There are no known contraindications to this drug when used as directed. Intra-arterial administration should be avoided. Horses inadvertently injected intraroterally can show adverse reactions. Signs can be ataxia, incoordination, hypertension, anion gap metabolic acidosis, and muscle weakness. Signs are transient and disappear without antidiotal medication within a few minutes. Do not use in horses showing hypersensitivity to flunixin meglumine.
Cattle:
NSAIDs inhibit production of prostaglandins which are important in signaling the initiation of parturition. The use of flunixin can delay parturition and prolong labor which may increase the risk of stillbirth. Do not use flunixin in cattle during the prostaglandin phase of the estrous cycle. The effects of flunixin on immanent parturition have not been evaluated in a controlled study. NSAIDs are known to have the potential to delay parturition through a tocolytic effect. Do not exceed the recommended dose.
PRECAUTIONS
As a class, cyclooxygenase inhibitory NSAIDs may be associated with gastrointestinal and renal toxicity. Sensitivity to drug-associated adverse effects varies with the individual patient. Patients at greatest risk for renal toxicity are those that are dehydrated, on concomitant diuretic therapy, or those with renal, cardiovascular, and/or hepatic dysfunction.
Since many NSAIDs possess the potential to induce gastrointestinal ulceration, concomitant use of FLUNIXAMINE Injectable Solution with other anti-inflammatory drugs, such as other NSAIDs and corticosteroids, should be avoided or closely monitored.
Horse:
The effect of FLUNIXAMINE Injectable Solution on pregnancy has not been determined. Studies to determine activity of FLUNIXAMINE Injectable Solution when administered concomitantly with other drugs have not been conducted. Drug compatibility should be monitored closely in patients requiring adjunctive therapy.
Cattle:
Do not use in bulls intended for breeding, as reproductive effects of FLUNIXAMINE Injectable Solution in these classes of cattle have not been investigated. NSAIDs are known to have potential effects on both parturition and the estrous cycle. There may be a delay in the onset of estrus if flunixin is administered during the prostaglandin phase of the estrous cycle. The effects of flunixin on imminent parturition have not been evaluated in a controlled study. NSAIDs are known to have the potential to delay parturition through a tocolytic effect. Do not exceed the recommended dose.
SAFETY
Horse:
A 3-fold intramuscular dose of 1.5 mg/kg of body weight daily for 10 consecutive days was safe. No changes were observed in hematology, serum chemistry, or urinalysis values. Intravenous dosages of 0.5 mg/kg daily for 15 days; 1.5 mg/lb daily for 10 days; and 2.5 mg/kg daily for 5 days produced no changes in blood or urine parameters. No injection site irritation was observed following intravenous injection of the 0.5 mg/kg recommended dose. Some irritation was observed following a 3-fold dose administered intramuscularly.
Cattle:
No flunixin-related changes (adverse reactions) were noted in cattle administered a 1X (2.2 mg/kg, 1.0 mg/lb) dose for 9 days (three times the maximum clinical duration). Minimal toxicity manifested itself at moderately elevated doses (3X and 5X) when flunixin was administered daily for 9 days, with occasional findings of blood in the feces and/or urine. Discontinue use if hematuria or fecal blood are observed.
ADVERSE REACTIONS
In horses, isolated reports of local reactions following intramuscular injection, particularly in the neck, have been received. These include localized swelling, sweating, induration, and stiffness. In rare instances in horses, fatal or nonfatal clostridial infections or other infections have been reported in association with intramuscular use of flunixin meglumine. In horses and cattle, rare instances of anaphylactic-like reactions, some of which have been fatal, have been reported, primarily following intravenous use.
HOW SUPPLIED
FLUNIXAMINE Injectable Solution, 50 mg/mL, is available in 100 mL and 250 mL multi-dose vials. Store between 2° and 30°C (36° and 86°F). PROTECT FROM FREEZING.
REFERENCES