Pr Ketoprofen V

Ketoprofen Injection 100 mg/mL
Sterile Injectable Solution
Nonsteroidal anti-inflammatory analgesic
For veterinary use only
DIN 02446316

Active ingredient: Each mL contains 100 mg ketoprofen; L-arginine 72 mg; benzyl alcohol 1% as a preservative; citric acid added to adjust pH.

Indications: Horses: Ketoprofen V is recommended for the alleviation of inflammation and pain associated with musculoskeletal disorders. Cattle: Ketoprofen V is recommended for the symptomatic treatment of fever, pain and inflammation associated with a variety of conditions including: respiratory tract infections, mastitis, udder edema, downer cow syndrome, endotoxemia, simple gastrointestinal disorders, arthritis and traumatic musculoskeletal injuries. Swine: Ketoprofen V is recommended for the treatment of fever and inflammation associated with respiratory infections.

Pharmacology: Ketoprofen is a nonsteroidal anti-inflammatory agent possessing anti-inflammatory, analgesic and antipyretic properties. Ketoprofen belongs to the propionic acid subclass of carboxylic acid derivative nonsteroidal antiinflammatory drugs, which also includes ibuprofen, naproxen and fenoprofen. The primary mechanism of action is inhibition of prostaglandin synthesis through interference with the cyclo-oxygenase pathway of arachidonic acid metabolism. Recent studies indicate that the analgesic and antipyretic effects are mediated centrally. Ketoprofen has been shown to have potent activity against acute, subacute and chronic inflammation in the classical models of inflammation. Ketoprofen has a high affinity for inflamed tissue, resulting in a therapeutic response which lasts considerably longer than can be predicted from the relatively short plasma half-life. Horses: Doses of ketoprofen ranging from 1 mg/kg (0.5 mg/lb) to 3 mg/kg (1.5 mg/lb) resulted in dose dependant anti-inflammatory effects in the chronic adjuvant carpitis model. Onset of activity is within two hours with peak response 12 hours after intravenous or intramuscular administration. Cattle: In well-controlled studies, beneficial effects have been demonstrated in a variety of disease conditions characterized by fever, inflammation and pain, including respiratory tract infections, mastitis, udder edema, downer cow syndrome, endotoxemia, simple gastrointestinal disorders, arthritis and traumatic musculoskeletal injuries. In diseases with a primary infectious etiology, ketoprofen should only be used in conjunction with appropriate antimicrobial therapy. Onset of activity is rapid. After administration of ketoprofen, peak plasma levels of ketoprofen and its primary metabolite are obtained in approximately 45 minutes and 3 hours, respectively. The plasma half-life is 2 hours. Eighty percent of the dose is eliminated in the urine within 24 hours following administration, primarily as the conjugated metabolite. Swine: In swine, as in other species, ketoprofen administered by intramuscular route is very rapidly and completely resorbed, peak plasma concentrations are obtained less than 1 hour after the injection. In diseases with a primary infectious etiology, ketoprofen should only be used in conjunction with appropriate antimicrobial therapy.

Toxicity: Horses: A 15-fold overdose of ketoprofen (30 mg/kg, 15 mg/lb) resulted in laminitis on the fifth day of treatment in one of two horses. A 25-fold overdose of ketoprofen (50 mg/kg, 25 mg/lb) produced inappetance, depression, icterus, recumbancy and abdominal swelling. Laboratory and necropsy examinations confirmed the presence of gastritis, nephritis and hepatitis. Doses of 2.2, 6.6 and 11.0 mg/kg (1, 3 and 5 mg/lb) given intravenously or intramuscularly for 15 days were well tolerated by horses, with no evidence of toxic effects compared to placebo treated horses. These doses are up to 5 times the recommended dose and 3 times the maximum recommended treatment duration. No adverse reactions and no toxic side effects were observed in clinical efficacy trials conducted in the U.S. in which 89 horses received a total of 445 ketoprofen injections at the recommended dose and duration. Cattle: Cattle treated with 5 times the recommended dose for 5 consecutive days exhibited no untoward treatment effects based on clinical and laboratory observations. At twice the recommended dose administered during the sixth week of gestation, or between the second and ninth month of gestation. Ketoprofen had no effect on course of gestation, parturition, fetal development or calf viability. Abomasal erosions were observed in young veal calves treated with three times the recommended dose for six consecutive days, but not when three times the recommended dose was administered for only three days. Ketoprofen injections are non-irritating and very well tolerated. In clinical trials, slight, transient edema was observed in approximately five percent of the injections administered. Swine: In swine after administration by intramuscular route of a single dose of 3 mg/kg or repeated doses (3 times at 24 h interval) of 3 or 9 mg/kg/day (one or three times the recommended dose-rate), the local and general tolerance of ketoprofen solution was excellent.

Dosage and administration: Horses: 2 mg/kg (1 mL/50 kg body weight) by intravenous or intramuscular injection, once a day for up to 5 days. Cattle: 3 mg/kg (1.5 mL/50 kg body weight) by intravenous or intramuscular injection, once a day for up to 3 days. Swine: 3 mg/kg (1.5 mL/50 kg bw) by intramuscular injection, once.

Contraindications: Do not use in animals showing hypersensitivity to ketoprofen. Do not administer to animals with impaired renal function.

Warnings: Cattle: Cattle treated with Ketoprofen V Injection at a dose rate of 3 mg/kg body weight/day for 3 consecutive days must not be slaughtered for use in food for at least 24 hours after the last treatment with this drug. Horses: Ketoprofen V Injection is not to be administered to horses that are to be slaughtered for use in food. Swine: Swine treated with Ketoprofen V Injection at a dose rate of 3 mg/kg bodyweight must not be slaughtered for use in food for at least 7 days after the last treatment with this drug.

Caution: General: Avoid intra-arterial injections. Due to its potent analgesic effect, Ketoprofen V may mask the signs of a serious colic/gastrointestinal problem which could require surgical correction. Horses: Ketoprofen has not been evaluated in foals and pony breeds, both of which are susceptible to NSAID induced gastrointestinal ulceration. Not intended for use in breeding animals as effects on fertility and reproductive function in mares and stallions have not been studied. Cattle: Antimicrobial therapy is imperative when Ketoprofen V is used as adjunctive therapy for fever and/or inflammation in conditions with an infectious etiology. Effects on fertility and reproductive function in breeding bulls have not been evaluated. Swine: Antimicrobial therapy is imperative when Ketoprofen V is used as adjunctive therapy for fever and/or inflammation in conditions with an infectious etiology.

How supplied: Ketoprofen V (ketoprofen injection 100 mg/mL) is available in 100 mL and 250 mL multiple dose vials.

Storage conditions: Store at controlled room temperature 15°-30°C (59°-86°F). Discard unused product after 28 days of first broaching the vial.
Protect from exposure to direct sunlight.

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