Ketoject

Injection

For Veterinary Use Only

COMPOSITION:
Each ml contains
Ketoprofen.....100mg

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 Ketoject 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, Ketoject should only be used in conjunction with appropriate antimicrobial therapy. Onset of activity is rapid. After administration of Ketoject, 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, Ketoject 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, Ketoject injection should only be used in conjunction with appropriate antimicrobial therapy.

TOXICOLOGY:
Horses: A 15-fold overdose of Ketoject (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 Ketoject (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 Ketoject 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. Ketoject 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. Ketoject 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 Ketoject injection was excellent.

INDICATIONS:
Ketoject injection is a potent, non-narcotic, non-steroidal anti-inflammatory agent with analgesic and anti-pyretic properties.
Horses: Ketoject injection is indicated for the alleviation of inflammation and pain associated with musculo – skeletal disorders. It is also indicated for the alleviation of visceral pain associated with colic.
Cattle: Ketoject injection is indicated for the supportive treatment of parturient paresis associated with calving, reducing pyrexia and distress associated with bacterial respiratory disease when used in conjunction with antimicrobial therapy as appropriate, improving the recovery rate in acute clinical mastitis, including acute endotoxin mastitis, reduces oedema of the udder associated with calving.
Swine: In swine, as in other species, Ketoject 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, Ketoject should only be used in conjunction with appropriate antimicrobial therapy.
DOSAGE AND ADMINISTRATION:
Horses: Administer the following dose by slow I/V injection Musculo-Skeletal Disorders:
1ml / 45kg once daily for up to 3 to 5 days.
Equine Colic:
1ml / 45kg once. A second injection may be given if colic recurs.
Cattle:
Administer the following dose by slow I/V or deep I/M injection 1ml / 33kg body weight once daily for up to 3-5 days.
WITHDRAWAL TIME:
Meat: 1 day for I/V Injection
Meat : 4 days for I/M Injection
PRECAUTIONS:
- Avoid using in pregnant mares
- Store between 15-25°C in a cool and dry place.
- Keep out of the reach of children.

BP Vet Specs.

Selmore Pharmaceuticals (Pvt) Ltd.

Manufactured by:
Selmore Pharmaceuticals (Pvt) Ltd.
36 Km Multan Road, Lahore, Pakistan.

ISO CERTIFIED COMPANY