Kelaprofen 100 mg/ml

injectable solution

COMPOSITION:

Ketoprofen 100 mg - Benzyl alcohol (E1519) 10 mg - Excipients up to 1 ml.

PROPERTIES:

Ketoprofen is a derivative of phenylpropionic acid, and belongs to the non steroidal anti-inflammatory group of drugs. Principal pharmacological actions are anti-inflammatory, analgesic and anti-pyretic. The mechanism of action is related to the ability of ketoprofen to interfere with the synthesis of prostaglandins from precursors such as arachidonic acid.
Ketoprofen is rapidly absorbed. The maximum plasma concentration is reached in less than an hour after parenteral administration. The bioavailability is about 80 to 95%.
Ketoprofen binds strongly to plasma proteins (about 95%), allowing its accumulation in the exudate at the site of inflammation.
The action is longer than what should be expected from the plasma half-life that varies between one and four hours depending on the species.
Ketoprofen enters the synovial fluid and remains there at higher levels than in plasma, with a half-life two to three times higher than in plasma.
Ketoprofen is metabolized in the liver and 90 percent is excreted in the urine and is complete after 96 hours.

TARGET SPECIES

Cattle, horse, pig.

INDICATIONS:

Cattle:

→ the supportive treatment of parturient paresis associated with calving;
→ reducing the 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, caused by Gram-negative micro-organisms, in conjunction with antimicrobial therapy;
→ reducing oedema of the udder associated with calving.

Horse:

→ the alleviation of inflammation and pain associated with musculoskeletal disorders;
→ the alleviation of visceral pain associated with colic.

Pig:

→ reducing the pyrexia and respiratory rate associated with bacterial or viral respiratory disease when used in conjunction with antimicrobial therapy as appropriate;

→ the supportive treatment of Mastitis Metritis Agalactia Syndrome in sows, in conjunction with antimicrobial therapy as appropriate.

CONTRA-INDICATIONS:

Do not use in animals with known hypersensitivity to the active substances or to any of the excipients.
Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other, corticosteroids, diuretics and anticoagulants.
Do not use in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, or where there is evidence of blood dyscrasia.

DOSAGE AND MODE OF ADMINISTRATION:

Use of a draw-off needle is recommended when treating large groups of animals.
Do not broach the container more than 33 times.

Cattle:

Intravenous or intramuscular administration.
3 mg ketoprofen/kg body weight, i.e. 1 ml of product per 33 kg body weight, administered by intravenous or deep intramuscular injection once daily for up to 3 days.

Horse:

Intravenous administration.
For use in musculo-skeletal conditions:
2.2 mg ketoprofen/kg i.e. 1ml of product per 45 kg body weight, administered by intravenous injection once daily for up to 3 to 5 days.

<u>For use in equine colic</u>:
2.2 mg/kg (1 ml/45 kg) body weight, given by intravenous injection for immediate effect. A second injection may be given if colic recurs.

Pig:

Intramuscular administration.
3 mg ketoprofen/kg body weight, i.e. 1ml of product per 33 kg body weight, administered once by deep intramuscular injection.

UNDESIRABLE EFFECTS:

In common with all NSAIDs, due to their action of inhibition of prostaglandin synthesis, there can be the possibility in certain individuals of gastric or renal intolerance. Allergic reactions may occur very rarely.

SPECIAL PRECAUTIONS FOR USE AND WARNINGS:

The use of ketoprofen is not recommended in foals under the age of 15 days.
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 management.
Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.
Avoid intra-arterial injection.
Do not exceed the stated dose or duration of treatment.
People with known hypersensitivity to the active substance and/or benzyl alcohol should avoid contact with this product.
In case of accidental self injection, seek medical advice and show the package leaflet or label to the physician.
Wash hands after use.
Avoid splashes on the skin and eyes. Wash affected area thoroughly with water should this occur. If irritation persists seek medical advice.

PACK SIZE:

Vials 50 ml, 100 ml, 250 ml.