D3 Proposed Package Leaflet

Ketosol 100mg/ml Solution for injection

Composition:
Contains per ml:
Ketoprofen …….... 100mg
Benzyl alcohol (preservative)……10mg

Controlled Medicine
Keep out of reach of children
Jauhi darikanak-kanak
MAL registration number

Product description:
Clear, slightly yellow, free from visible suspended particles

Pharmacodynamics:
Ketoprofen is a derivative of phenylpropionicacid, and belongs to the non- steroidal anti-inflammatory drugs. Like all such substances, its 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.

Pharmacokinetics:
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.

Indication:
Horse
- the alleviation of inflammation and pain associated with musculoskeletal disorders;
- the alleviation of visceral pain associated with colic.

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.

Pigs
- 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.

Recommended dose:
Use of a draw-off needle is recommended when treating large groups of animals.
Do not broach the container more than 33 times.
Horse:
Intravenous administration.
For use in musculo-skeletal conditions:
2.2 mg ketoprofen/kg i.e. 1 ml of product per 45 kg body weight, administered by intravenous injection once daily for up to 3 to 5 days.
For use in equine colic:
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.
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.
Pigs:
Intramuscular administration.
3 mg ketoprofen/kg body weight, i.e. 1 ml of product per 33 kg body weight, administered once by deep intramuscular injection.

Contraindication:

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

Warning and Precautions:

Special warnings for each target species

None.

Special precautions for use

Special precautions for use in animals

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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

People with known hypersensitivity to the active substance and/or benzyl alcohol should avoid contact with the veterinary medicinal product.

In case of accidental self-injection, seek medical advice and show the package leaflet or the 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.

Interaction of other medicaments:

Do not administer with other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other, corticosteroids, diuretics or anticoagulants.

Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.

Concurrent administration with nephrotoxic drugs should be avoided.

Pregnancy and Lactation:

The safety of Ketoprofen has been investigated in pregnant laboratory animals (rats, mice and rabbits) and in cattle, and showed no teratogenic or embryotoxic effects. The product may be given to pregnant and to lactating cattle and to lactating sows. As the effects of ketoprofen on the fertility, pregnancy or foetal health of horses have not been determined, the product should not be administered to pregnant horses. As the safety of ketoprofen has not been assessed in pregnant sows, the product should be used in these cases only according to a benefit/risk assessment by the responsible veterinarian.

Side Effects:

In very rare cases, due to the action of inhibition of prostaglandin synthesis, there can be the possibility in certain individuals of gastric or renal intolerance.

In very rare cases allergic reactions may occur.

The frequency of adverse reactions is defined using the following convention:

- Very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment).
- Common (more than 1 but less than 10 animals in 100 animals).
- Uncommon (more than 1 but less than 10 animals in 1,000 animals).
- Rare (more than 1 but less than 10 animals in 10,000 animals).
- Very rare (less than 1 animal in 10,000 animals, including isolated reports).

Symptoms and treatment of overdose:

No clinical signs were observed when ketoprofen was administered to horses at 5 times the recommended dose for 15 days, to cattle at 5 times the recommended dose for 5 days, or to pigs at 3 times the recommended dose for 3 days.

Withdrawal period:

Cattle:

Meat and offal:

- following intravenous administration: 1 day
- following intramuscular administration: 2 days

Milk: zero hours

Horses:
Meat and offal: 1 day
Milk: Not authorised for use in lactating animals producing milk for human consumption
Pigs:
Meat and offal: 2 days

Storage condition:
Store below 30°C and do not refrigerate or freeze.

Packaging:
50 and 100ml of amber type II glass injection vials closed with a rubber stopper and an aluminium cap.

Manufacturer:
Interchemie werken "De Adelaar" Eesti AS
Vanapere tee 14, Püünsi village, Viimsi municipality, Harju country, 74013 Estonia.

Marketing Authorization Holder:
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