PACKAGE INSERT FOR KETINK SOLUTION FOR INJECTION

VETERINARY MEDICINE

SCHEDULING STATUS

S3

PROPRIETY NAMES AND DOSAGE FORMS

KETINK (SOLUTION FOR INJECTION)

COMPOSITION

Each ml contains Ketoprofen 100 mg [10 % m/v].

PRESERVATIVE

Each ml contains 1 % m/v Benzyl Alcohol as preservative

PHARMACOLOGICAL CLASSIFICATION

C3.1 Anti-rheumatics (Anti-inflammatory agents).

PHARMACOLOGICAL ACTION

Ketoprofen is a non-steroidal anti-inflammatory agent with analgesic and antipyretic activity.

Pharmacodynamic properties

Ketoprofen is a substance belonging to the group non-steroidal anti-inflammatory drugs (NSAIDs). Ketoprofen has anti-inflammatory, analgesic, and antipyretic properties. Not all aspects of its mechanism of action are known. Effects are obtained partially by the inhibition of prostaglandin and leukotriene synthesis by ketoprofen, acting on cyclooxygenase and lipoxygenase respectively. The formation of bradykinin is also inhibited. Ketoprofen inhibits thrombocyte aggregation.

Pharmacokinetic particulars

After intravenous injection to horses the half-life is approx. 1 hour. The distribution volume is approx.0.17 l/kg and the clearance approx. 0.3 l/kg. After intramuscular injection to cattle and pigs ketoprofen is quickly absorbed and the maximum plasma concentration of approx. 11 micrograms/ml is obtained within ½ to 1 hour. The mean absorption time is approx. 1 hour. The plasma half-life is 2 – 2 ½ hours.

The bioavailability after intramuscular injection is 90 – 100% in cattle and pigs. In the case of repeated injections at 24 hour intervals ketoprofen exhibits linear and stationary kinetics since the above parameters remain unchanged. Ketoprofen is approx. 95% bound to plasma proteins.

Ketoprofen is metabolised mainly by the reduction of the ketone group to a main metabolite. Ketoprofen is quickly excreted; approx. 80% is eliminated within 12 hours after administration. 90% of the elimination takes place via the kidneys, mainly in metabolised form.

INDICATIONS

Horses: Anti-inflammatory and analgesic treatment of musculo-skeletal disorders. Symptomatic analgesic treatment of visceral pain.

Cattle: Anti-inflammatory, anti-pyretic in cases of musculo-skeletal conditions. Use as an adjunct to the treatment of acute respiratory conditions, mastitis and other inflammatory conditions.

Pigs: Treatment of inflammatory conditions i.e. mastitis – metritis – agalactia syndrome (MMA) and respiratory infections. Alleviation of fever.

CONTRAINDICATIONS

Do not administer to animals with gastro-duodenal ulcers or haemorrhagic syndrome.

Do not administer to animals with severe renal insufficiency.

Do not administer to animals with a bleeding tendency.

Do not use when previous allergy to ketoprofen has occurred.

Do not administer by intra-arterial route

WARNINGS

KEEP OUT OF REACH OF CHILDREN AND UNIFORMED PERSONS.

INTERACTIONS

Do not mix with another substance.

Do not use with another non-steroidal anti-inflammatory. (NSAIDS) drugs or with diuretics or anticoagulants

PREGNANCY AND LACTATION

As the effects of ketoprofen on fertility, pregnancy or foetal health in horses have not been determined, KETINK should not be administered to pregnant mares.

KETINK may be given to pregnant and lactating cattle and is indicated for use in lactating sows. The effect of treatment during the parturient period has not been investigated

Do not use in foals that are less than 15 days old.

Do not administer to horses destined for human consumption.

Withdrawal periods

Cattle (edible tissues): 1-day intravenous route
4 days intramuscular route
Pigs (edible tissues): 4 days
Cattle (Milk): Milk discard time of nil hours

DOSAGE AND DIRECTIONS FOR USE

Horses
For musculo-skeletal inflammation and pain: administer 2,2 mg of active ingredient per kg body mass daily for 3 to 5 consecutive days, by intravenous or intramuscular route, i.e. 1 ml per 45 kg.
For visceral pain associated with colic: administer 2,2 mg of active ingredient per kg. i.e. 1 ml per 45 kg body mass. A single intravenous injection is usually sufficient. Any further injections should be considered after reconsideration of the diagnosis.

Cattle:
Administer 3 mg of active ingredient per kg body mass, daily for 1 to 3 consecutive days, by intramuscular or intravenous route, i.e. 3 ml per 100 kg.
Pigs:
Give one injection of 3 mg of active ingredient per kg body mass, i.e., 3 ml per 100 kg by intramuscular route.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS

Side effects typical of non-steroidal anti-inflammatory agents such as gastro-intestinal ulceration and nephrotoxicity may occur.

KNOWN SYMPTOMS OF OVERDOSE AND PARTICULARS OF ITS TREATMENT

Gastro-intestinal and nephrotoxicity is related to duration of treatment.
Treatment is supportive.

IDENTIFICATION

Clear, colourless solution (not more intensely coloured than reference Y6).

PRESENTATION

100 ml type II multi-dose amber glass bottle with a grey bromobutyl rubber stopper and grey aluminium seal and white flip-off cap. Each bottle is placed inside a cardboard carton.
250 ml type II multi-dose amber glass bottle with a pink bromobutyl rubber stopper and grey aluminium seal and white flip-off cap. Each bottle is placed inside a cardboard carton.

The cardboard cartons are packed in a bulk carton which contains 6, 10 or 12 units of 100 ml or 250 ml bottles.

STORAGE INSTRUCTIONS

Store at or below 25 °C.
Protect from light and heat.
Keep the glass bottle in the packaging ? until required for use.
Once opened the product can be stored up to 28 days at or below 25 °C.
After 28 days all unused portions should be discarded.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER

17/3.1/03

NAME AND BUSINESS ADDRESS OF HOLDER OF THE CERTIFICATE OF REGISTRATION

Afrivet Business Management (Pty) Ltd
Dawie Street, Newmark Estate,
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10 August 2022