

**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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### **DATE OF PUBLICATION OF THIS PACKAGE INSERT**

10 August 2022