Patient Leaflet for a veterinary product

The medicine is marketed according to a Veterinary Doctor prescription only

For Animal use only

1. NAME OF THE VETERINARY MEDICINAL PRODUCT, DOSAGE FORM AND STRENGTH

Ketoprosol Veterinary, solution for injection

2. Active substance and its quantity per unit dose: Ketoprofen 100 mg/ml

Excipients: Benzyl alcohol 10 mg/ml.

For the full list of excipients, see section 13 of this leaflet.

3. What is this medicine used for

Horses:

- 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 an 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.

Therapeutic group: Non-Steroidal Anti Inflammatory Drugs (NSAID)

4. Contraindications

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.

5. Side effects

In very rare cases (less than 1 animal in 10,000 animals), 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 (less than I animal in 10,000 animals), allergic reactions may occur.

Side effects can be reported to the Ministry of Health by clicking on the link "Adverse Drug Reactions Report" that appears on the home page of the Ministry of Health web site (www.health.gov.il) which leads to an online form for reporting side effects. Alternatively you can use the following link: https://sideeffects.health.gov.il/

6. Target species: Horses, cattle.

7. Dosage and administration route

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.

8. How to use the product

Use of a draw-off needle is recommended when treating large groups of animals.

Do not broach the container more than 33 times.

9. Withdrawal periods in Cattle

Meat:

- following intravenous administration: 2 day
- following intramuscular administration: 4 days

Milk: no Withdrawal period

10. Warnings

- Special precautions for use of the medicine in treatment of the target animal

  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 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.

- Pregnancy and lactation of the treated Animal

  The safety of Ketoprofen has been investigated in 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. 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.

- Interaction with other medicinal products and other forms of interaction

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

  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.

- Overdose -No clinical signs were observed when ketoprofen was administered to horses at 5 times the recommended dose for 15 days, or to cattle at 5 times the recommended dose for 5 days.
- Incompatibility: In the absence of compatibility studies, this medicinal product must not be mixed with other substances in the same syringe.

11. Instructions for storage

- Avoid poisoning! This medicine and all other medicines should be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning.
- Do not use this medicine after the expiry date (exp. date) stated on the package. The expiry date relates to the last day of that month.
- Storage conditions: To be stored below 25°C packed into the original container. Protect from light.
- Shelf life after first opening of the immediate packaging: 28 days, should be stored below 25°C.

12. Directions for the disposal of unused product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of as toxic waste, do not throw in the sewer.

13. Additional information

In addition to the active substance, the medicine also contains L-Arginine, Benzyl Alcohol, Citric Acid Monohydrate (for pH adjustment), Water for Injection

What the medicine looks like and contents of the pack- clear, yellow solution in amber vial of 50 and 100 ml, closed with rubber stopper and aluminum cap, packed in an outer carton. Not all pack sizes may be marketed.

Manufacturer: CP-Pharma Handelsgesellschaft mbH, Ostlandring 13, 31303 Burgdorf, Germany.

License Holder: Hachaklait Ltd., 20 Habareket St., Zone 24, POB 3039, Ceasarea Industrial Park, 38900.

Revised in October 2021 according to MOHs guidelines.

Registration number of the medicinal product in the National Drug Registry of the Ministry of Health: 168-39-35918-00