

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kelaprofen 10% Veterinary

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per ml

Active substance:

Ketoprofen 100 mg

Excipients:

Benzyl alcohol (E1519) 10 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection
Clear solution.

4. CLINICAL PARTICULARS

4.1 Target species

Horses, cattle.

4.2 Indications for use, specifying the target species

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.

4.3 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.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

(i) 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.

(ii) 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.

4.6 Adverse reactions (frequency and seriousness)

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).

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form: [/https://sideeffects.health.gov.il](https://sideeffects.health.gov.il)

4.7 Use during pregnancy, lactation or lay

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. 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.

4.8 Interaction with other medicinal products and other forms of interaction

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.

4.9 Amounts to be administered and administration route

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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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.

4.11 Withdrawal periods

Cattle:

Meat and offal:

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

Milk: zero hours

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory, antirheumatic products, non-steroids, propionic acid derivatives.

ATCvet code: QM01AE03

5.1 Pharmacodynamic properties

Ketoprofen is a derivative of phenylpropionic acid, 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.

5.2 Pharmacokinetic properties

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

L-Arginine
Benzyl Alcohol (E1519)
Citric Acid Monohydrate (for pH adjustment)
Water for Injection

6.2 Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other substances in the same syringe.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials Shelf life after first opening of the immediate packaging: 28 days, should be stored below 25°C.

6.4 Special precautions for storage

Do not refrigerate or freeze.
To be stored up to 30°C packed into the original container. Protect from light.

6.5 Nature and composition of immediate packaging

Nature of the container:
Amber glass vials type II of 50, 100 and 250 ml, closed with bromobutyl rubber stoppers and aluminum caps, packed in an outer carton.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal 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 in accordance with local requirements.

7. Manufacturer:

KELA N.V.
St. Lenaartseweg 48
2320 Hoogstraten
BELGIUM

License Holder:

ROMAT LTD., HA'MAAPILIM 39/104, HERZLIYA 46543

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