

SUMMARY OF PRODUCT CHARACTERISTICS

KELAPROFEN 100 mg/ml (AT, BE, BG, CY, CZ, DE, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, NL, PT, RO, SK, UK)

KETOKEL VET 100 mg/ml (NO)

VETAPROFEN 100 mg/ml (PL)

KELAFEN 100 mg/ml (DK)

FENPROKEL VET 100 mg/ml (FI, SE)

KELA N.V.

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kelaprofen 100 mg/ml, solution for injection for cattle, horses and pigs (AT, BE, BG, CY, CZ, DE, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, NL, PT, RO, SK, UK)

Ketokel vet 100 mg/ml, solution for injection for cattle, horses and pigs (NO)

Vetaprofen 100 mg/ml, solution for injection for cattle, horses and pigs (PL)

Kelafen 100 mg/ml, solution for injection for cattle, horses and pigs (DK)

Fenprokel vet 100 mg/ml, solution for injection for cattle, horses and pigs (FI, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

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, colourless or yellowish solution.

4. CLINICAL PARTICULARS

4.1 Target species

Horses, cattle, pigs.

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;
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- 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.
- Reducing pain associated with lameness

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.

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

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.

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

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 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.

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.

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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 breach 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.

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, to cattle at 5 times the recommended dose for 5 days, or to pigs at 3 times the recommended dose for 3 days.

4.11 Withdrawal periods

Cattle:

Meat and offal:

- following intravenous administration: 1 day

- following intramuscular administration: 2 days

Milk: zero hours

Horses:

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Meat and offal: 1 day

Milk: Not authorised for use in lactating animals producing milk for human consumption

Pigs:

Meat and offal: 2 days

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.

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6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf life after first opening of the immediate packaging: 28 days.

6.4 Special precautions for storage

Do not refrigerate or freeze.
Protect from light.

6.5 Nature and composition of immediate packaging

Amber glass vials type II of 50, 100 and 250 ml, closed with bromobutyl rubber stoppers and aluminium caps, packed in an outer carton.

Package sizes:

Carton boxes with 1, 6, 10 and 12 vials of 50 ml, 100 ml and 250 ml.

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. MARKETING AUTHORISATION HOLDER

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

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8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation:

Date of last renewal:

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only - to be supplied only on veterinary prescription.

To be administered only by a veterinary surgeon (ES).