KETOFEN®10%

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Product information

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1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketofen 10%.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml contains:

Active(s) substance(s):

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.

4. CLINICAL PARTICULARS

4.1 | Target species

Cattle, swine and equine.

4.2 | Indications for use, specifying the target species

In Cattle:

Treatment of inflammation, pain and fever notably in respiratory infections, mammary oedema, musculo-skeletal conditions: assitance in rising after parturition, lameness, arthritis (in complement to etiological treatment), trauma, dystocia.

Swine:

Reduction of pyrexia in respiratory diseases and in mastitis-metritis-agalactiae syndrome when administered with appropriate antimicrobial therapy.

Sport and race horses:

Treatment of inflammation and pain in osteo-articular and musculosqueletical system disorders, in particular lameness of traumatic origin, arthrosis, arthritis, osteitis, eparvin, navicular disease, tendinitis, bursitis, laminitis, myositis, post-surgical inflammations.

Symptomatic analgesic treatment of colics.

4.3 | Contraindications

Administration of ketoprofen is contraindicated in case of severe renal insufficiency and in association with other NSAIDs, diuretics or anticoagulants.

Do not apply to animal that has already developed an hypersensitivity phenomenon to ketoprofen.

4.4 | Special warnings for each target species

None.

4.5 | Special precautions for use

i Special precautions for use in animals

Do not mix with other substance.

In the absence of data on specific tolerance for very young foal, the use of the preparation is not recommended for foals under the age of 15 days.

ii Special precautions to be taken by the person administering the veterinary medicinal product to animals

In case of self-injection, seek medical assistance.

Avoid contact with eyes and skin. If necessary rinse immediately with water.

Wash hands after use.

iii Other precautions

None.

4.6 | Adverse reactions (frequency and seriousness)

Not known.

4.7 | Use during pregnancy, lactation or lay

Studies on laboratory animals (rat, rabbit) do not show teratogenic or embryotoxic effects of ketoprofen.

However, due to lack of studies in pregnant mare and sow, it is recommended not to use the product during pregnancy.

4.8 | Interaction with other medicinal products and other forms of interaction

Do not use at the same time as other NSAIDs, corticosteroids, diuretics or anticoagulants.

4.9 | Amounts to be administered and administration route

Cattle:
Intravenous or intramuscular route.
3 mg of ketoprofen per kg bodyweight daily, i.e. 3 ml of solution per 100 kg bodyweight daily for 1-3 consecutive days

Pigs:
Intramuscular route
3 mg ketoprofen per kg bodyweight daily, i.e. 3 ml of solution per 100 kg bodyweight in one injection.

Horses:
Intravenous or intramuscular route.
2.2 mg of ketoprofen per kg bodyweight daily, i.e. 1 ml of solution per 45 kg body weight.

- Inflammation and pain of osteoarticular and musculosqueletical systems: 3 to 5 consecutive days via intravenous or intramuscular route.
- Colic: one injection as intravenous is generally sufficient. Any additional injection must be only after new clinical evaluation of the animal.

Stopper should not be punctionned more than 45 times. To treat a huge number of animals at once, automatic syringe can be used.

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

No adverse events have been reported at doses higher than the recommended ones.

4.11 | Withdrawal period(s)

Swine and horses:
Meat and offals : 4 days.

Bovine:
Meat and offals: 4 days.
Milk: 0 day.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Propionic acid and derivatives.
ATC-Vet Code: QMO1AE03.

5.1 | Pharmacodynamic properties

Ketoprofen is a non-steroidal anti-inflammatory drug having high anti-inflammatory, analgesic, and antipyretic activity.
It acts by inhibiting prostaglandin and leukotrienes synthesis.
Classical tests for evaluation of anti-inflammatory and analgesic activity show the net superiority of ketoprofen on aspirine and phenlbutazone.

5.2 | Pharmacokinetic particulars

After injection, ketoprofen is rapidly absorbed. Maximum plasmatic concentrations are obtained within about one hour. Bioavailability is about 80 to 95%. Persistence of ketoprofen in blood is low. Contrary to plasmatic concentrations, concentrations of ketoprofen in inflammatory sites remain flat and high at least for 30 to 36 hours after one intravenous injection.
Elimination, essentially via urine, is completed within 96 hours.

6. PHARMACEUTICAL PARTICULARS

6.1 | List of excipients

Benzyl alcohol (E1519)
Arginine
Citric acid monohydrate (for pH adjustment)
Water for injectable preparations

6.2 | Major incompatibilities

Do not mix with other substance.

6.3 | Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening of the immediate packaging: 28 days.

6.4 | Special precautions for storage

None.

6.5 | Nature and composition of immediate packaging

Type II colored glass vial.
Chlorobutyl stopper.
Aluminium capsule.

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.