

LABIPROFEN

150 MG/ML SOLUTION FOR INJECTION FOR CATTLE, PIGS AND HORSES

Ketoprofen 150 mg/ml

DATA
SHEET



INDICATIONS FOR USE

Cattle:

- Reduction of inflammation and pain associated with post-partum, musculoskeletal disorders and lameness.
- Reduction of fever associated with bovine respiratory disease in combination with antimicrobial therapy where appropriate.
- Reduction of inflammation, fever and pain in acute clinical mastitis in combination with antimicrobial therapy where appropriate.

Pigs:

- Reduction of pyrexia in cases of respiratory disease and Postpartum Dysgalactia Syndrome PDS- (Metritis Mastitis Agalactia syndrome) in sows, in combination with antimicrobial therapy, where appropriate.

Horses:

- Reduction of inflammation and pain associated with osteoarticular and musculoskeletal disorders (lameness, laminitis, osteoarthritis, synovitis, tendinitis, etc.).
- Reduction of postoperative pain and inflammation.
- Reduction of visceral pain associated with colic.

BENEFITS

- Ketoprofen 150mg/ml anti-inflammatory (10ml dose for 500kg cow)
- Zero hours milk withdrawal in cattle
- For use via intramuscular or intravenous route in cattle
- High bioavailability and maximum level reached with an hour in cattle via IM administration
- Anti-pyretic and analgesic activity for use in multiple species



LIST No

1LAB001

UNIT PACKAGE

100ml

See reverse for Administration & Dosage

Labiprofen

150 mg/ml solution for injection for cattle, pigs and horses

Ketoprofen 150 mg/ml



ACTIVE SUBSTANCE

Ketoprofen 150 mg/ml. Solution for injection. A clear colourless to yellowish solution

TARGET SPECIES

Cattle, pigs and horses

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Pigs:

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Horses:

- Reduction of inflammation and pain associated with osteoarthritis and musculoskeletal disorders (lameness, laminitis, osteoarthritis, synovitis, tendinitis, etc.).
- Reduction of postoperative pain and inflammation.
- Reduction of visceral pain associated with colic.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

Cattle: Intramuscular or intravenous use

3 mg ketoprofen/kg body weight, i.e., 1ml of product per 50 kg body weight/ day, administered via the intravenous or intramuscular route, preferably in the neck region.

The duration of treatment is 1-3 days and should be established according to the severity and duration of symptoms.

Pigs: Intramuscular use

3 mg of ketoprofen/kg body weight i.e., 1 ml of the product per 50 kg body weight/ day, administered via the intramuscular route on a single occasion. Depending on the response observed and based on the benefit-risk analysis by the responsible veterinarian treatment may be repeated at intervals of 24 hours for a maximum of three treatments. Each injection should be given at a different site.

Horses: Intravenous use

2.2 mg of ketoprofen/kg body weight, i.e., 0.75 ml of the product, per 50 kg body weight/ day, administered via the intravenous route.

The duration of treatment is 1-5 days and should be established according to the severity and duration of symptoms. In the case of colic one injection is normally sufficient. A second administration of ketoprofen requires a clinical re-examination.

WITHDRAWAL PERIODS

Cattle:

Meat and offal: 2 days

Milk: zero hours

Horses:

Meat and offal: 1 day

Milk: Not authorised for use in mares producing milk for human consumption

Pig:

Meat and offal: 3 days

CONTRAINDICATIONS

Do not use in animals where there is the possibility of gastro-intestinal ulceration or bleeding, in order not to aggravate their situation. Do not use in animals suffering from cardiac, hepatic, or renal disease. Do not use in cases of known hypersensitivity to ketoprofen or acetyl-salicylic acid or to any of the excipients. Do not use in animals with evidence of blood dyscrasia or coagulopathy. Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.

SPECIAL WARNINGS FOR EACH TARGET SPECIES

None.

SPECIAL PRECAUTIONS FOR USE IN ANIMALS

Do not exceed the recommended dose. Do not exceed the recommended treatment period.

The use of ketoprofen is not recommended in foals less than one month of age. When administering to animals of less than 6 weeks of age, ponies or in aged animals it is necessary to adjust the dose accurately as well as to perform a close clinical follow-up.

AVOID INTRA-ARTERIAL INJECTION

Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.

Since gastric ulceration is a common finding in PMWS (Post-weaning Multisystemic Wasting Syndrome), the use of ketoprofen in pigs affected by this pathology is not recommended,

in order not to aggravate their situation.

In horses, avoid extravascular administration.

SPECIAL PRECAUTIONS TO BE TAKEN BY THE PERSON ADMINISTERING THE VETERINARY MEDICINAL PRODUCT

Hypersensitivity reactions (skin rash, urticaria) could occur. People with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the veterinary medicinal product. Avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Avoid contact with the skin, eyes and mucous membranes. In case of accidental skin, eye or mucous membrane contact, wash the affected area thoroughly with clean running water immediately. Seek medical advice if irritation persists. Wash hands after use.

ADVERSE REACTIONS

Intramuscular injection of ketoprofen can cause mild, transient, necrotic subclinal muscular lesions that gradually resolve in the days after completion of treatment. Administration in the neck region minimizes the extension and severity of these lesions.

In horses, transient local reactions, which disappeared after 5 days, were observed after one administration of the product at the recommended volume by extravascular route.

Due to the mechanism of action of ketoprofen, after repeated administrations, erosive and ulcerative lesions of the gastrointestinal tract may occur.

In common with all NSAIDs due to their action of inhibition of prostaglandins synthesis, there can be the possibility in certain individuals of gastric or renal intolerance.

If side effects occur treatment must be stopped, and the advice of a veterinarian should be sought.

USE DURING PREGNANCY OR LACTATION

Pregnancy:

Studies in laboratory animals (rats, mice, rabbits) and cattle have not produced any evidence of adverse effects. Can be used in pregnant cows.

The safety of the veterinary medicinal product has not been established during pregnancy in sows and mares. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Lactation:

Can be used in lactating cows and sows. The use is not recommended in lactating mares.

INTERACTION WITH OTHER MEDICINAL PRODUCTS

- Concurrent administration of diuretics or potentially nephrotoxic drugs should be avoided since there is an increase of renal disturbances, including renal failure. This is secondary to the diminished blood flow caused by the inhibition of prostaglandins synthesis.

- Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, anticoagulants or diuretics concurrently or within 24 hours of administration of the product since the risk of gastrointestinal ulceration and other adverse reactions may be exacerbated.

- The treatment free period should however take into account the pharmacological properties of the products used previously.

- Ketoprofen is highly bound to plasma proteins and may compete with other highly bound drugs which can lead to toxic effects.

OVERDOSE

Overdose with non-steroidal anti-inflammatory drugs can lead to gastro-intestinal ulceration, loss of proteins, hepatic and renal impairment.

In tolerance studies performed in pigs, up to 25% of the animals treated at three times the maximum recommended dose (9 mg/kg bw) for three days or at the recommended dose (3 mg/kg bw) for triple the maximum recommended time (9 days) showed erosive and/or ulcerative lesions in both the aglandular (pars oesophagica) and glandular parts of the stomach. Early signs of toxicity include loss of appetite and pasty faeces or diarrhoea.

The intramuscular administration of the product to cattle, at up to 3 times the recommended dose or for 3 times the recommended duration of the treatment (9 days) did not result in clinical signs of intolerance. However, inflammation as well as necrotic subclinal lesions were detected at the injection site of the treated animals as well as an increase in CPK levels. The histopathological examination showed erosive or ulcerative abomasal lesions related to both dosage regimes.

Horses have been found to tolerate intravenous dosages of ketoprofen up to 5 times the recommended dose for three times the recommended duration (15 days) with no evidence of toxic effects.

If clinical signs of overdose are observed, there is no specific antidote, therefore symptomatic treatment should be initiated.

PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and

Antirheumatic Products, Non-Steroids, Propionic acid derivatives. Ketoprofen, 2-(phenyl 3-benzoyl) propionic acid is a non-steroidal anti-inflammatory drug belonging to the arylpropionic acid group. The primary mechanism of action for ketoprofen is considered to be inhibition of the cyclooxygenase pathway of arachidonic acid metabolism, leading to decreased production of inflammatory mediators, such as prostaglandins and thromboxanes. This mechanism of action results in its anti-inflammatory, anti-pyretic and analgesic activity. These properties are also attributed to its inhibiting effect on bradykinin and superoxide anions together with its stabilizing action on lysosomal membranes.

The anti-inflammatory effect is enhanced by the conversion of the (R)-enantiomer to (S)enantiomer. It is known that the (S)-enantiomer supports the anti-inflammatory effect of ketoprofen.

PHARMACOKINETIC PARTICULARS

After intramuscular administration of the product (single dose of 3 mg ketoprofen/kg body weight), ketoprofen is rapidly absorbed, and has a high bioavailability.

Ketoprofen binds extensively to plasma proteins (>90%).

The concentrations of Ketoprofen are more sustained in inflammatory exudates than in plasma. It reaches high concentrations and persists in inflamed tissue, due to the fact that Ketoprofen is a weak acid. Ketoprofen is metabolized in the liver to inactive metabolites and it is excreted mainly in urine (primarily as glucuroconjugated metabolites) and, to a lesser extent, in faeces.

Small amounts of ketoprofen can be detected in the milk of treated animals.

In cattle, following the intramuscular administration of the product (single dose of 3 mg ketoprofen/kg body weight), the active drug substance is rapidly absorbed, reaching its average C_{max} in plasma (mean value: 7.2 µg/ml) between 0.5 and 1 hour (t_{max}) after initiation of treatment. The fraction of dose absorbed is very high (92.51±10.9%).

Following the intravenous administration in cattle, elimination half-life ($t_{1/2}$) is of 2.1 h. The distribution volume (Vd) of 0.41 L/kg, and plasma clearance (Cl) of 0.14 L/h/kg.

In pigs, following the intramuscular injection of a single dose of 3 mg/ketoprofen/kg body weight, the active drug substance is rapidly absorbed, reaching its average C_{max} in plasma (mean value: 16 µg/ml) between 0.25 and 1.5h (t_{max}) after initiation of the treatment. The fraction of dose absorbed is 84.7±33%.

Following the intravenous administration in pigs, elimination half-life ($t_{1/2}$) is of 3.6 h. The distribution volume (Vd) of 0.15 L/kg, and plasma clearance (Cl) of 0.03 L/h/kg.

In horses Ketoprofen is 92.8% protein bound and it has a moderate Vd of approximately 0.5 L/kg and short plasma elimination half-lives of 1 to 1.5 hours. The active substance is hepatically metabolized by conjugation reactions, with only 25% of a dose eliminated as unchanged in urine. The maximum anti-inflammatory effects of ketoprofen occur at 4 hours after a dose and last for 24 hours, illustrating that the anti-inflammatory effects are not related to plasma concentrations in horses.

MAJOR INCOMPATIBILITIES

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

SHELF-LIFE

Shelf-life of the veterinary medicinal product as packaged for sale: 30 months

Shelf-life after first opening the immediate packaging: 28 days

SPECIAL PRECAUTIONS FOR STORAGE

Keep the vial in the outer carton in order to protect from light.

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED VETERINARY MEDICINAL PRODUCTS

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

DISTRIBUTED BY

Bimeda Animal Health Limited
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MARKETING AUTHORISATION HOLDER

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MARKETING AUTHORISATION NUMBER

VPA10402/005/001

LEGAL CATEGORY

POM

TAKE TIME



OBSERVE LABEL DIRECTIONS

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