NEFOTEK

Ketoprofen 100mg/ml solution for injection for cattle, horses and pigs

DATA SHEET

INDICATIONS

- **Cattle:** Anti-inflammatory and analgesic treatment of diseases in the musculoskeletal system and the udder.

- **Horses:** Anti-inflammatory and analgesic treatment of diseases in the musculoskeletal system and joints.

  Symptomatic analgesic treatment for colic, postoperative pain and swelling.

- **Pigs:** Anti-inflammatory and antipyretic treatment of Postpartum Dysgalactia Syndrome–PDS–(Metritis Mastitis Agalactia Syndrome) and respiratory diseases.

BENEFITS

- **Licensed for use in cattle, horses and pigs**
- **Suitable for intra-muscular administration in cattle and pigs**
- **Short 4 day meat withdrawal in all species**
- **ZERO days milk withdrawal in cattle**

LIST No	UNIT PACKAGE	CASE SIZE
1NEF001	100ml	10

See reverse for Administration & Dosage

NEFOTEK

100mg/ml Solution for Injection for Cattle, Horses and Pigs

PRESENTATION
A clear, colourless to yellow solution for injection (Free from visible particles)
1ml contains; 100 mg ketoprofen (active substance)

Excipients: Benzyl alcohol (E1519) 10 mg (for full list please see SPC)

TARGET SPECIES
Cattle, pigs and horses

USES
Cattle: Anti-inflammatory and analgesic treatment of diseases in the musculoskeletal system and the udder.
Pigs: Anti-inflammatory and antipyretic treatment of Postpartum Dysgalactia Syndrome –PDS - (Metritis Mastitis Agalactia Syndrome) and respiratory diseases.
Horses: Anti-inflammatory and analgesic treatment of diseases in the musculoskeletal system and joints.
Symptomatic analgesic treatment for colic, postoperative pain and swelling.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE
Cattle: Intramuscular use or Intravenous use
3 mg ketoprofen/kg b.w/day (equivalent to 3 ml of the product /100 kg b.w/day) for up to 3 days.
Pigs: Intramuscular use only
3 mg ketoprofen/kg b.w./day (equivalent to 3 ml of the product /100 kg b.w./day) administered once.
Horses: Intravenous use only
2.2 mg ketoprofen/kg b.w./day (equivalent to 1 ml of the product /45 kg b.w./day) for 3 to 5 days. In the case of colic, treatment should not be repeated until a clinical re-examination has been carried out.
No more than 5 ml should be administered at one intramuscular injection site.
The stoppers must not be punctured more than 166 times.

CONTRAINDICATIONS AND WARNINGS
Do not use in case of hypersensitivity to the active substance, or to any of the excipients.
Do not use in animals suffering from gastro-intestinal lesions, haemorrhagic diathesis, blood dyscrasia, impaired hepatic, cardiac or renal function.
Do not use in foals in their first month of life.
Do not use other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.
Use in animals 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 intra-arterial injection. Do not exceed the stated dose or duration of treatment.
Use with caution in dehydrated, hypovolemic or hypotensive animals as there is a potential risk of increased renal toxicity. In the case of colic a supplementary dose may only be given after a thorough clinical examination.
Sufficient drinking water must be supplied at all times during treatment.
Special precautions to be taken by the person administering the veterinary medicinal product to animals
Take care to 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.
People with known hypersensitivity to ketoprofen or benzyl alcohol should avoid contact with the veterinary medicinal product.
Avoid splashes on the skin and eyes. Rinse thoroughly with water should this occur. If irritation persists seek medical advice. Wash hands after use.

USE DURING PREGNANCY AND LACTATION
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 effect 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 case according to the benefit/risk assessment by the responsible veterinarian.

ADVERSE REACTIONS
In very rare cases (less than 1 animal in 10,000 animals, including isolated reports) these signs can be observed: temporary irritation after repeated intramuscular injections; gastric and intestinal irritation or ulceration (due to ketoprofen mechanism of action including inhibition of prostaglandin synthesis); reversible inappetence after repeated administration to swine; allergic reactions.

INTERACTION WITH OTHER MEDICINAL PRODUCTS AND OTHER FORMS OF INTERACTION
Nefotek must not be administered in conjunction with, or within 24 hours of administration of other NSAIDs and glucocorticoids. Concurrent administration of diuretics, nephrotoxic drugs and anticoagulative drugs should be avoided.
Ketoprofen is highly bound to plasma proteins, and may displace or be displaced by other highly protein bound medicines, such as anticoagulants. Due to the fact that ketoprofen may inhibit platelet aggregation and cause gastrointestinal ulceration, it should not be used with other medicines that have the same profile of adverse drug reactions.

OVERDOSE (SYMPTOMS, EMERGENCY PROCEDURES, ANTIDOTES)
No clinical signs were observed when the product was administered to horses at 5 times (11 mg/kg) the recommended dose for 15 days, to cattle at 5 times (15mg/kg/day) the recommended dose for 5 days, or to pigs at 3 times (9mg/kg/day) the recommended dose for 3 days.

PHARMACODYNAMIC PROPERTIES
Ketoprofen is a non-steroidal anti-inflammatory drug (NSAID). Ketoprofen has anti-inflammatory, analgesic and antipyretic properties. Not all aspects of its mechanism of action are known. Effects are obtained partially by the inhibition of prostaglandin and leukotriene synthesis by ketoprofen, acting on cyclooxygenase and lipoxygenase respectively. The formation of bradykinin is also inhibited. Ketoprofen inhibits thrombocyte aggregation.

WITHDRAWAL PERIOD(S)
Cattle, horses, pigs:
Meat and offal: 4 days
Milk (bovine): Zero hours
Not authorised for use in mares producing milk for human consumption.

PHARMACOKINETIC PARTICULARS
After intravenous injection to horses the half-life is approx. 1 hour. The distribution volume is approx. 0.17 l/kg and the clearance approx. 0.3 l/kg. After intramuscular injection to cattle and pigs ketoprofen is quickly absorbed and the maximum plasma concentration of approx. 11 micrograms/ml is obtained within ½ to 1 hour. The mean absorption time is approx. 1 hour. The plasma half-life is 2 – 2 ½ hours. The bioavailability after intramuscular injection is 90 – 100% in cattle and pigs. In the case of repeated injections at 24 hour intervals ketoprofen exhibits linear and stationary kinetics since the above parameters remain unchanged. Ketoprofen is approx. 95% bound to plasma proteins.
Ketoprofen is metabolised mainly by the reduction of the ketone group to a main metabolite. Ketoprofen is quickly excreted; approx. 80% is eliminated within 12 hours after administration. 90% of the elimination takes place via the kidneys, mainly in metabolised form.

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: 2 years.
Shelf life after first opening the immediate packaging: 28 days.

EXCIPIENTS
L Arginine, Benzyl alcohol (E1519), Citric acid monohydrate (for pH adjustment).
Water for injection.

STORAGE
Keep the container in the outer carton. Protect from light. Do not refrigerate or freeze.

DISPOSAL
Any unused or waste materials derived from the product should be disposed of in accordance with local requirements.

LEGAL CATEGORY
POM-V

MARKETED IN THE UK BY
Bimeda UK
Unit 2, Bryn Cefni Industrial Park
Llangefni, Anglesey,
Wales, LL777XA
Tel: +44 (0) 1248 725 400

MARKETING AUTHORISATION NUMBER
VM 32509/4008

Use Medicines Responsibly.
Noah.co.uk/responsible

TAKE TIME  OBSERVE LABEL DIRECTIONS

www.bimeda.co.uk

Bimeda data sheet created: January 2021