1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketodolor 100 mg/ml solution for injection for horses, cattle, pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Ketoprofen 100 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Benzyl alcohol (E1519)	10 mg
L-arginine	
Citric acid monohydrate (for pH adjustment)	
Water for injections	

Clear, near colourless to light yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle, pigs.

3.2 Indications for use for each target species

Horses:
- alleviation of inflammation and pain associated with musculoskeletal disorders;
- alleviation of visceral pain associated with colic.

Cattle:
- alleviation of pain (e.g. from pressure trauma) resulting from parturient paresis;
- reduction of the pyrexia and distress associated with bacterial respiratory disease when used in conjunction with antimicrobial therapy as appropriate;
- improvement of the recovery rate in acute clinical mastitis, including acute endotoxin mastitis, caused by gram negative micro-organisms, in conjunction with antimicrobial therapy;
- alleviation of pain associated with udder oedema following calving.
- reduction of pain associated with lameness.

Pigs:
- reduction of the pyrexia and respiratory rate associated with bacterial or viral respiratory disease when used in conjunction with antimicrobial therapy as appropriate.
- supportive treatment of Mastitis Metritis Agalactia Syndrome in sows, in conjunction with antimicrobial therapy as appropriate.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.
Do not use in animals suffering from gastro-intestinal lesions, haemorrhagic diathesis, blood dyscrasia, impaired hepatic, cardiac or renal function.
Please refer to section 3.7.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.
The use of ketoprofen is not recommended in foals under the age of 15 days.
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
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 and/or benzyl alcohol should avoid contact with the veterinary medicinal product.
Avoid splashes on the skin and eyes. Wash the affected area thoroughly with water should this occur. If irritation persists seek medical advice.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Horses, cattle, pigs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Stomach disorder[a] Renal disorder[a]

[a] Intolerance. Due to the mechanism of action of NSAIDs (inhibition of prostaglandin synthesis).

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 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.

Pregnancy, lactation and fertility:

Can be used in pregnant and lactating cattle, and lactating sows.
As the effects of ketoprofen on the fertility, pregnancy or foetal health of horses have not been determined, the veterinary medicinal product should not be administered to pregnant horses.
As the safety of ketoprofen has not been assessed in pregnant sows, use only according to the benefit-risk assessment by the responsible veterinarian.

3.8 Interaction with other medicinal products and other forms of interaction

The veterinary medicinal product 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.

3.9 Administration routes and dosage

Horse: intravenous use.
For use in musculo-skeletal conditions, the recommended dosage is 2.2 mg ketoprofen/kg i.e. 1 ml of the veterinary medicinal product /45 kg body weight, administered once daily for up to 3 to 5 days.

For use in equine colic, the recommended dosage is 2.2 mg/kg (1 ml/45 kg) body weight, given for immediate effect. A second injection may be given if colic recurs.

Cattle: *intravenous use or deep intramuscular use.*
The recommended dose is 3 mg ketoprofen/kg body weight, i.e. 1 ml of the veterinary medicinal product/33 kg body weight, administered once daily for up to 3 days.

Pigs: deep intramuscular use.
The recommended dose is 3 mg ketoprofen/kg body weight, i.e. 1 ml of the veterinary medicinal product /33 kg body weight, administered once.

The stopper cannot be punctured more than 20 times.

To ensure a correct dosage, body weight should be determined as accurately as possible.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No clinical signs were observed when ketoprofen was administered to horses at 5 times the recommended dose (11 mg/kg) for 15 days, to cattle at 5 times the recommended dose (15 mg/kg/day) for 5 days, or to pigs at 3 times the recommended dose (9 mg/kg/day) for 3 days.
In cases of overdose, a symptomatic treatment is required.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable

3.12 Withdrawal periods

Cattle
Meat and offal: following intravenous use - 1 day.
following intramuscular use - 4 days.

Milk: zero hours.

Pigs
Meat and offal: 4 days.

Horses
Meat and offal: 1 day.
Milk: Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :
QM01AE03

4.2 Pharmacodynamics

Ketoprofen is a derivative of phenylpropionic acid, and belongs to the non steroidal anti-inflammatory group of 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.

Following intravenous injection in the horse, the onset of musculo-skeletal anti-inflammatory activity occurs by 2 hours, and reaches a peak at about 12 hours. It is still measurable 24 hours after each dose.

4.3 Pharmacokinetics

Ketoprofen binds 95% to plasma proteins.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

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

5.3 Special precautions for storage

Do not refrigerate or freeze.
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

The product is packed in amber type II glass vials of 50 ml or 100 ml, fitted with red chlorobutyl stoppers and aluminium caps.
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.,

7. MARKETING AUTHORISATION NUMBER(S)

VPA10475/00/001

8. DATE OF FIRST AUTHORISATION

17/05/2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

30/07/2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).