SUMMARY OF PRODUCT CHARACTERISTICS

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 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 yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Horses, cattle, pigs

4.2 Indications for use,specifying the 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.

4.3 Contraindications

Do not use in cases of hypersensitivity to the active substance(s) or to any of the excipient(s).
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 4.7.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
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 and show the package leaflet or the label to the physician.
People with known hypersensitivity to the active substance and/or benzyl alcohol should avoid contact with the 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.

4.6 Adverse reactions (frequency and seriousness)

In common with all NSAIDs, due to their action of inhibition of prostaglandin synthesis, cases of of gastric or renal intolerance have been observed very rarely.

The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals treated displaying adverse reaction(s)
- Common (more than 1 but less than 10 animals in 100 animals treated)
- Uncommon (more than 1 but less than 10 animals in 1000 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 according to a benefit/risk assessment by the responsible veterinarian.

4.8 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.

4.9 Amounts to be administered and administration route

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

For use in equine colic, the recommended dosage is 2.2mg/kg (1ml/45kg) 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 3mg ketoprofen/kg body weight, i.e. 1ml of the product/33kg body weight, administered once daily for up to 3 days.

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

The stopper cannot be punctured more than 20 times.

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 (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.

4.11 Withdrawal period(s)

Cattle

meat and offal:	following intravenous administration - 1 day following intramuscular administration - 4 days
milk:	zero hours

Pigs

meat and offal:	4 days

Horses

meat and offal:	1 day
milk:	not authorized for use in lactating animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiinflammatory and antirheumatic products, non-steroids
ATCvet code: QM01AE03

5.1 Pharmacodynamic properties

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.

5.2 Pharmacokinetic particulars

Ketoprofen binds 95% to plasma proteins.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl alcohol (E1519)
L-arginine

Citric acid monohydrate (for pH adjustment)
Water for injections

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

6.4 Special precautions for storage

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

6.5 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.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 41821/4004

9. DATE OF FIRST AUTHORISATION

27 June 2013

10. DATE OF REVISION OF THE TEXT

November 2018

Approved: 28 November 2018