PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Ketoprofen 100 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

Horses, Cattle, Pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached , use by…
Shelf-life after first opening the vial: 28 days.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only - to be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 41821/4004

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING UNITS

Amber glass vials of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ketoprofen 100 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses, Cattle, Pigs

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Horse: IV
Cattle: IV/IM
Pigs: IM

8. WITHDRAWAL PERIOD

Withdrawal period:

Cattle (meat and offal):	IV - 1 day IM - 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

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached , use by…

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 41821/4004

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Amber glass flasks of 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Ketoprofen 100 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTE(S) OF ADMINISTRATION

Horse: IV
Cattle: IV/IM
Pigs: IM

5. WITHDRAWAL PERIOD

Cattle (meat and offal):	IV - 1 day IM - 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

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once broached, use by…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

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

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for batch release:
Produlab Pharma B.V.
Forellenweg 16
4941 SJ Raamsdonksveer
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:
Ketoprofen 100 mg

Excipients:
Benzyl alcohol (E1519) 10 mg

The product is a clear yellow solution.

4. INDICATION(S)

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.

5. 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.

6. ADVERSE REACTIONS

In common with all NSAIDs, due to their action of inhibition of prostaglandin synthesis, cases 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)

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses, Cattle, Pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD

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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not refrigerate or freeze.
Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after EXP. The expiry date refers to the last day of that month.

Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

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

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.

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.

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.

The product has been safely given to calves as young as 3 days of age, and to pregnant and lactating cattle.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

1x1 vial of 50 ml
1x1 vial of 100 ml
Not all pack sizes may be marketed.

Approved: 28 November 2018