A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Ketoprofen 100 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml – 100 ml – 250 ml

5. TARGET SPECIES

Horse, cattle, pig

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

Cattle: intravenous or deep intramuscular use
Horses: intravenous use
Pigs: deep intramuscular use
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:
Meat and offal:
- following intravenous administration: 1 day
- following intramuscular administration: 2 days

Milk: zero hours

Horses:
Meat and offal: 1 day

Milk: Not authorised for use in lactating animals producing milk for human consumption

Pigs:
Meat and offal: 2 days

9. SPECIAL WARNING, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Shelf life after first opening the container: 28 days.
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.
Protect from light.

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

Dispose of waste material in accordance with local requirements.

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.
To be administered only by a veterinary surgeon (ES).

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

Kela N.V.
St. Lenaartseweg 48
2320 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06126/3000

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE

Each ml contains:

Active substance:
Ketoprofen 100 mg

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

50 ml

4. ROUTES OF ADMINISTRATION

Cattle: intravenous or deep intramuscular use
Horses: intravenous use
Pigs: deep intramuscular use
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:
Meat and offal:
- following intravenous administration: 1 day
- following intramuscular administration: 2 days

Milk: zero hours

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

Pigs:
Meat and offal: 2 days

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

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

Once broached, use by:…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 100 – 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Ketoprofen 100 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml – 250 ml

5. TARGET SPECIES

Horse, cattle, pig

6. INDICATION(S)

7. METHOD AND ROUTES OF ADMINISTRATION

Cattle: intravenous or deep intramuscular use
Horses: intravenous use
Pigs: deep intramuscular use

Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:
Meat and offal:
- following intravenous administration: 1 day
- following intramuscular administration: 2 days

Milk: zero hours

Horses:

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

Pigs:
Meat and offal: 2 days

9. SPECIAL WARNING, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

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

Once broached, use by:…

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.
Protect from light.

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

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

Kela N.V.
St. Lenaartseweg 48
2320 Hoogstraten
Belgium

16. MARKETING AUTHORISATION NUMBER(S)

Vm 06126/3000

17. MANUFACTURER'S BATCH NUMBER

Lot:

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Kelaprofen 100 mg/ml Solution for Injection for Cattle, Horses and 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 and manufacturer responsible for batch release:
Kela N.V.
St. Lenaartseweg 48
2320 Hoogstraten
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substance:
Ketoprofen 100 mg

Excipients:
Benzyl alcohol (E1519) 10 mg

Clear, colourless or yellowish solution

4. INDICATIONS

Horse
- the alleviation of inflammation and pain associated with musculoskeletal disorders;
- the alleviation of visceral pain associated with colic.

Cattle
- the supportive treatment of parturient paresis associated with calving;
- reducing the pyrexia and distress associated with bacterial respiratory disease when used in conjunction with antimicrobial therapy as appropriate;
- improving the recovery rate in acute clinical mastitis, including acute endotoxin mastitis, caused by Gram-negative micro-organisms, in conjunction with antimicrobial therapy;
- reducing oedema of the udder associated with calving.
- Reducing pain associated with lameness

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

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to the active substance or to any of the excipients.

Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other, corticosteroids, diuretics and anticoagulants.

Do not use in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, or where there is evidence of blood dyscrasia.

6. ADVERSE REACTIONS

In very rare cases, due to the action of inhibition of prostaglandin synthesis, there can be the possibility in certain individuals of gastric or renal intolerance.
In very rare cases allergic reactions may occur.
Mild inflammatory reactions at the injection site, such as swelling/oedema, without pain in most cases have been reported, based on post-marketing safety experience.
The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals treated displaying adverse reaction(s) during the course of one treatment).
- Common (more than 1 but less than 10 animals in 100 animals treated).
- Uncommon (more than 1 but less than 10 animals in 1,000 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

Horse, cattle, pig

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Use of a draw-off needle is recommended when treating large groups of animals.
Do not broach the container more than 33 times.

Horse:
Intravenous administration.
For use in musculo-skeletal conditions:

2.2 mg ketoprofen/kg i.e. 1 ml of product per 45 kg body weight, administered by intravenous injection once daily for up to 3 to 5 days.

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

Cattle:
Intravenous or intramuscular administration.
3 mg ketoprofen/kg body weight, i.e. 1 ml of product per 33 kg body weight, administered by intravenous or deep intramuscular injection once daily for up to 3 days.

Pigs:
Intramuscular administration.
3 mg ketoprofen/kg body weight, i.e. 1 ml of product per 33 kg body weight, administered once by deep intramuscular injection.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIODS

Cattle:
Meat and offal:
- following intravenous administration: 1 day
- following intramuscular administration: 2 days

Milk: zero hours

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

Pigs:
Meat and offal: 2 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not refrigerate or freeze.
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.
When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package insert, the date on which any product remaining in the container should be discarded should be worked out. This discard date should be written in the space provided on the label.

12. SPECIAL WARNINGS

Special precautions for use in animals:
The use of ketoprofen is not recommended in foals under the age of 15 days.
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. 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:
People with known hypersensitivity to the active substance and/or benzyl alcohol should avoid contact with the veterinary medicinal product. In case of accidental self-injection, seek medical advice and show the package leaflet or the label to the physician. Wash hands after use. Avoid splashes on the skin and eyes. Wash affected area thoroughly with water should this occur. If irritation persists seek medical advice.

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 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 only according to a benefit/risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
Do not administer with other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other, corticosteroids, diuretics or anticoagulants. Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.
Concurrent administration with nephrotoxic drugs should be avoided.

Overdose (symptoms, emergency procedures, antidotes):
No clinical signs were observed when ketoprofen was administered to horses at 5 times the recommended dose for 15 days, to cattle at 5 times the recommended dose for 5 days, or to pigs at 3 times the recommended dose for 3 days.

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

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements. (national requirement UK/IE only)

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

May 2022

15. OTHER INFORMATION

Package sizes:
Carton boxes with 1, 6, 10 and 12 vials of 50 ml, 100 ml and 250 ml.

Not all pack sizes may be marketed.

PROHIBITION OF SALE, SUPPLY AND/OR USE

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

Approved: