ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kelaprofen 100 mg/ml solution for injection for cattle, horses and pigs (AT, BE, BG, CY, CZ, DE, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, NL, PT, RO, SK, UK(NI))

Ketokel vet 100 mg/ml solution for injection for cattle, horses and pigs (NO)

Vetaprofen 100 mg/ml solution for injection for cattle, horses and pigs (PL)

Kelafen 100 mg/ml solution for injection for cattle, horses and pigs (DK)

Fenprokel vet 100 mg/ml solution for injection for cattle, horses and pigs (FI, SE)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:
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
Arginine	
Citric acid monohydrate (for pH adjustment)	
Water for injections	

Clear, colourless or yellowish solution.

3. CLINICAL INFORMATION

3.1 Target species

Horses, cattle, pigs.

3.2 Indications for use for each target species

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.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substances 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.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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:
The active substance ketoprofen and the excipient benzyl alcohol may cause hypersensitivity (allergy). People with known hypersensitivity to the active substance and/or benzyl alcohol should avoid contact with the veterinary medicinal product.
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.
Avoid contact withthe skin and eyes. In case of accidental skin or eyes contact, wash the affected area thoroughly with water. If irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.
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):	Allergic reaction Gastritis[1] Renal disorder[1]

[1] due to the action of inhibition of prostaglandin synthesis, gastric or renal intolerance is possible in certain individuals

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

Pregnancy:

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. Can be used during pregnancy in cows.

The safety of ketoprofen has not been established during pregnancy in sows. Use only according to the benefit-risk assessment by the responsible veterinarian.

The safety of ketoprofen on the fertility, pregnancy or foetal health of horses has not been established. Do not use during pregnancy in mares. t

Lactation:

Can be used during lactation in cows and sows.

3.8 Interaction with other medicinal products and other forms of interaction

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.

3.9 Administration routes and dosage

Horse:
Intravenous use (i.v.).
For use in musculo-skeletal conditions:
2.2 mg ketoprofen/kg i.e. 1 ml of the veterinary medicinal 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 use (i.v. or i.m.).
3 mg ketoprofen/kg body weight, i.e. 1 ml of the veterinary medicinal product per 33 kg body weight, administered by intravenous or deep intramuscular injection once daily for up to 3 days.

Pigs:
Intramuscular use (i.m.).
3 mg ketoprofen/kg body weight, i.e. 1 ml of the veterinary medicinal product per 33 kg body weight, administered once by deep intramuscular injection.

Use of a draw-off needle is recommended when treating large groups of animals.

Do not broach the container more than 33 times.

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 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.

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 administration: 1 day.
- following intramuscular administration: 2 days.

Milk: zero hours.

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

Pigs:
Meat and offal: 2 days.

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 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.

4.3 Pharmacokinetics

Ketoprofen is rapidly absorbed. The maximum plasma concentration is reached in less than an hour after parenteral administration. The bioavailability is about 80 to 95%. Ketoprofen binds strongly to plasma proteins (about 95%), allowing its accumulation in the exudate at the site of inflammation.
The action is longer than what should be expected from the plasma half-life that varies between one and four hours depending on the species. Ketoprofen enters the synovial fluid and remains there at higher levels than in plasma, with a half-life two to three times higher than in plasma.
Ketoprofen is metabolized in the liver and 90 percent is excreted in the urine and is complete after 96 hours.

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: 30 months.
Shelf life after first opening of the immediate packaging: 28 days.

5.3 Special precautions for storage

Do not refrigerate or freeze.

Protect from light.

5.4 Nature and composition of immediate packaging

Amber glass vials type II closed with bromobutyl rubber stoppers and aluminium caps, packed in an outer carton.

Package sizes:
Carton box with 1 vial of 50 ml.
Carton box with 6 vials of 50 ml.
Carton box with 10 vials of 50 ml.
Carton box with 12 vials of 50 ml.
Carton box with 1 vial of 100 ml.
Carton box with 6 vials of 100 ml.
Carton box with 10 vials of 100 ml.
Carton box with 12 vials of 100 ml.
Carton box with 1 vial of 250 ml.
Carton box with 6 vials of 250 ml.
Carton box with 10 vials of 250 ml.
Carton box with 12 vials of 250 ml

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

Kela nv

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorisation:

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

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).

ANNEX III

LABELLING AND PACKAGE LEAFLET

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 (AT, BE, BG, CY, CZ, DE, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, NL, PT, RO, SK, UK(NI))

Ketokel vet 100 mg/ml solution for injection (NO)

Vetaprofen 100 mg/ml solution for injection (PL)

Kelafen 100 mg/ml solution for injection (DK)

Fenprokel vet 100 mg/ml solution for injection (FI, SE)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Ketoprofen 100 mg

3. PACKAGE SIZE

1 x 50 ml
6 x 50 ml
10 x 50 ml
12 x 50 ml
1 x 100 ml
6 x 100 ml
10 x 100 ml
12 x 100 ml
1 x 250 ml
6 x 250 ml
10 x 250 ml
12 x 250 ml

4. TARGET SPECIES

Horses, cattle, pigs

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: intravenous or deep intramuscular use (i.v. or deep i.m.)
Horses: intravenous use (i.v.)
Pigs: deep intramuscular use (i.m.)

7. WITHDRAWAL PERIODS

Withdrawal periods:

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

Milk: zero hours.

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

Pigs:
Meat and offal: 2 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.
Once broached, use by …

9. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.

Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Kela nv

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kelaprofen (AT, BE, BG, CY, CZ, DE, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, NL, PT, RO, SK, UK(NI))

Ketokel vet (NO)

Vetaprofen (PL)

Kelafen (DK)

Fenprokel vet (FI, SE)

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

ketoprofen 100 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.
Once broached, use by …

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

LABEL 100 – 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AT, BE, BG, CY, CZ, DE, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, NL, PT, RO, SK, UK(NI):
Kelaprofen 100 mg/ml solution for injection

NO:
Ketokel vet 100 mg/ml solution for injection

PL:
Vetaprofen 100 mg/ml solution for injection

DK:
Kelafen 100 mg/ml solution for injection

FI, SE:
Fenprokel vet 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Ketoprofen 100 mg

3. TARGET SPECIES

Horses, cattle, pigs

4. ROUTES OF ADMINISTRATION

Cattle: intravenous or deep intramuscular use (i.v. or deep i.m.)
Horses: intravenous use (i.v.)
Pigs: deep intramuscular use (i.m.)

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

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 animals producing milk for human consumption.

Pigs:
Meat and offal: 2 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days.
Once broached, use by …

7. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.

Protect from light.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Kela nv

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

1. Name of the veterinary medicinal product

Kelaprofen 100 mg/ml solution for injection for cattle, horses and pigs (AT, BE, BG, CY, CZ, DE, EE, EL, ES, FR, HR, HU, IE, IT, LT, LU, NL, PT, RO, SK, UK (NI))

Ketokel vet 100 mg/ml solution for injection for cattle, horses and pigs (NO)

Vetaprofen 100 mg/ml solution for injection for cattle, horses and pigs (PL)

Kelafen 100 mg/ml solution for injection for cattle, horses and pigs (DK)

Fenprokel vet 100 mg/ml solution for injection for cattle, horses and pigs (FI, SE)

2. Composition

Each ml contains:

Active substance:
Ketoprofen 100 mg

Excipients:
Benzyl alcohol (E1519) 10 mg

Clear, colourless or yellowish solution

3. Target species

Horses, cattle, pigs

4. Indications for use

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 cases of 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. Special warnings

Special precautions for safe use in the target species:
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:
The active substance ketoprofen and the excipient benzyl alcohol may cause hypersensitivity (allergy). People with known hypersensitivity to the active substance and/or benzyl alcohol should avoid contact with the veterinary medicinal product. 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. Avoid contact with the skin and eyes. In case of accidental skin or eyes contact, wash the affected area thoroughly with water. If irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician. Wash hands after use.

Pregnancy:
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. Can be used during pregnancy in cows.
The safety of ketoprofen has not been established during pregnancy in sows. Use only according to the benefit-risk assessment by the responsible veterinarian.
The safety of ketoprofen on the fertility, pregnancy or foetal health of horses has not been established. Do not use during pregnancy in mares.

Lactation:
Can be used during lactation in cows and sows.

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:
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.

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

7. Adverse events

Horses, cattle, pigs

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

[1] due to the action of inhibition of prostaglandin synthesis, gastric or renal intolerance is possible in certain individuals

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or its local representative using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Horse:
Intravenous use (i.v.).
For use in musculo-skeletal conditions:
2.2 mg ketoprofen/kg i.e. 1 ml of the veterinary medicinal 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 use (i.v. or i.m.).
3 mg ketoprofen/kg body weight, i.e. 1 ml of the veterinary medicinal product per 33 kg body weight, administered by intravenous or deep intramuscular injection once daily for up to 3 days.

Pigs:
Intramuscular use (i.m.).
3 mg ketoprofen/kg body weight, i.e. 1 ml of the veterinary medicinal product per 33 kg body weight, administered once by deep intramuscular injection.

9. Advice on correct administration

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

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 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 immediate packaging: 28 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Amber glass vials type II of 50, 100 and 250 ml, closed with bromobutyl rubber stoppers and aluminium caps, packed in an outer carton.

Package sizes:
Carton box with 1 vial of 50 ml.
Carton box with 6 vials of 50 ml.
Carton box with 10 vials of 50 ml.
Carton box with 12 vials of 50 ml.
Carton box with 1 vial of 100 ml.
Carton box with 6 vials of 100 ml.
Carton box with 10 vials of 100 ml.
Carton box with 12 vials of 100 ml.
Carton box with 1 vial of 250 ml.
Carton box with 6 vials of 250 ml.
Carton box with 10 vials of 250 ml.
Carton box with 12 vials of 250 ml.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Kela nv
Sint Lenaartseweg 48
2320 Hoogstraten
Belgium
Tel: +32 3 340 04 11
E-mail: info@kela.health

Local representatives and contact details to report suspected adverse events:

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information