BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: Ketoprofen, 100 mg; Benzyl alcohol (E1519), 10 mg.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
250 ml
6 x 100 ml
6 x 250 ml
10 x 100 ml
10 x 250 ml
12 x 100 ml
12 x 250 ml

5. TARGET SPECIES

Cattle, pigs and horses.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: Intramuscular use or Intravenous use
Pigs: Intramuscular use
Horses: Intravenous use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle, horses, pigs:
Meat and offal: 4 days
Milk (bovine): Zero hours

Not authorised for use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Take care to avoid accidental self injection

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 28 days.

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.
Protect from light.
Do not refrigerate or freeze.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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

Industrial Veterinaria, S.A.
Esmeralda 19
E-08950 Esplugues de Llobregat
Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 36547/4001

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

LABEL VIAL OF 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: Ketoprofen, 100 mg; Benzyl alcohol (E1519), 10 mg.

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, pigs and horses.

6. INDICATION

Read the package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

Cattle: Intramuscular use or Intravenous use
Pigs: Intramuscular use
Horses: Intravenous use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle, horses, pigs:
Meat and offal: 4 days
Milk (bovine): Zero hours
Not authorised for use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Take care to avoid accidental self injection

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 28 days.
Once opened use by.

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton. Protect from light.
Do not refrigerate or freeze.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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

Industrial Veterinaria, S.A.
Esmeralda 19
E-08950 Esplugues de Llobregat
Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 36547/4001

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

LABEL VIAL OF 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketink 100 mg/ml solution for injection for cattle, horses and pigs[Austria, Bulgaria, Cyprus, Czech Republic, Estonia, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, United Kingdom]
Ainil 100 mg/ml solution for injection for cattle, horses and pigs [Denmark]
Aristal 100 mg/ml solution for injection for cattle, horses and pigs [Belgium]

Ketoprofen

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains: Ketoprofen, 100 mg; Benzyl alcohol (E1519), 10 mg.

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

250 ml

5. TARGET SPECIES

Cattle, pigs and horses.

6. INDICATION

Read the package leaflet before use.

7. METHOD AND ROUTE OF ADMINISTRATION

Cattle: Intramuscular use or Intravenous use
Pigs: Intramuscular use
Horses: Intravenous use
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Cattle, horses, pigs:
Meat and offal: 4 days
Milk (bovine): Zero hours
Not authorised for use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Take care to avoid accidental self injection

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 28 days.
Once opened use by .

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton. Protect from light.
Do not refrigerate or freeze.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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

Industrial Veterinaria, S.A.
Esmeralda 19
E-08950 Esplugues de Llobregat
Barcelona
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 36547/4001

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PACKAGE LEAFLET FOR:

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

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

Marketing authorisation holder:
Industrial Veterinaria, S.A.
Esmeralda 19
E-08950 Esplugues de Llobregat
Barcelona
Spain

Manufacturer responsible for batch release:
Industrial Veterinaria, S.A.
Esmeralda 19
08950 Esplugues de Llobregat (Barcelona) Spain

aniMedica GmbH
Im Südfeld 9
48308 Senden-Bösensell Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

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

Each ml contains: Ketoprofen, 100 mg; Benzyl alcohol (E1519), 10 mg.
A clear, colourless to yellow solution. Free from visible particles.

4. INDICATIONS

Cattle: Anti-inflammatory and analgesic treatment of diseases in the musculoskeletal system and the udder.
Pigs: Anti-inflammatory and antipyretic treatment of Postpartum Dysgalactia Syndrome -PDS- (Metritis Mastitis Agalactia Syndrome)and respiratory diseases.
Horses: Anti-inflammatory and analgesic treatment of diseases in the musculoskeletal system and joints.
Symptomatic analgesic treatment for colic. Postoperative pain and swelling.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance, or to any of the excipients.

Do not use in animals suffering from gastro-intestinal lesions, haemorrhagic diathesis, blood dyscrasia, impaired hepatic, cardiac or renal function.
Do not use in foals in their first month of life.
Do not use other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.

6. ADVERSE REACTIONS

In very rare cases these signs can be observed:

- temporary irritation after repeated intramuscular injections.
- gastric and intestinal irritation or ulceration (due to ketoprofen mechanism of action including inhibition of prostaglandin synthesis).
- reversible inappetence after repeated administration to swine.
- allergic reactions.

The frequency of adverse reactions is defined using the following convention:
- Very common (more than 1 in 10 animals displaying adverse reaction(s) during the course of one treatment).
- Common (more than 1 but less than 10 animals in 100 animals).
- Uncommon (more than 1 but less than 10 animals in 1,000 animals).
- Rare (more than 1 but less than 10 animals in 10,000 animals).
- Very rare (less than 1 animal in 10,000 animals, including isolated reports).

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, pigs and horses.

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

Cattle: Intramuscular use or Intravenous use
3 mg ketoprofen/kg body weight/day(equivalent to 3 ml of the product/100 kg b.w./day)for up to 3 days.
Pigs: Intramuscular use
3 mg ketoprofen/kg body weight/day(equivalent to 3 ml of the product/100 kg b.w./day) administered once.
Horses: Intravenous use
2.2 mg ketoprofen/kg body weight/day(equivalent to 1 ml of the product/45 kg b.w./day)for 3 to 5 days.
In the case of colic, treatment should not be repeated until a clinical re-examination has been carried out.

9. ADVICE ON CORRECT ADMINISTRATION

Not more than 5 ml should be administered at one intramuscular injection site.
The stoppers must not be punctured more than 166 times.

10. WITHDRAWAL PERIOD

Cattle, horses, pigs:
Meat and offal: 4 days
Milk (bovine): Zero hours
Not authorised for use in mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Keep the container in the outer carton.
Protect from light.
Do not refrigerate or freeze.
Do not use after the expiry date which is stated on the label.
Shelf life after first opening the immediate packaging: 28 days.

12. SPECIAL WARNINGS

Special precautions for use in animals
Use in animals 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 intra-arterial injection. Do not exceed the stated dose or duration of treatment.
Use with caution in dehydrated, hypovolemic or hypotensive animals as there is a potential risk of increased renal toxicity. In the case of colic a supplementary dose may only be given after a thorough clinical examination.
Sufficient drinking water must be supplied at all times during treatment.

User Warnings
Take care to 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.
People with known hypersensitivity to ketoprofen or benzyl alcohol should avoid contact with the veterinary medicinal product.
Avoid splashes on the skin and eyes. Rinse 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)
No clinical signs were observed when the product was administered to horses at 5 times (11 mg/kg) the recommended dose for 15 days, to cattle at 5 times (15 mg/kg/day) the recommended dose for 5 days, or to pigs at 3 times (9 mg/kg/day) the recommended dose for 3 days.
Ketoprofen can lead to hypersensitivity reactions and moreover might have a detrimental effect on the gastric mucosa. This may require cessation of ketoprofen treatment and introduction of symptomatic therapy.

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

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

January 2021

15. OTHER INFORMATION

Ketoprofen is a substance belonging to the group non-steroidal anti-inflammatory drugs (NSAIDs). Ketoprofen has anti-inflammatory, analgesic and antipyretic properties. Not all aspects of its mechanism of action are known. Effects are obtained partially by the inhibition of prostaglandin and leukotriene synthesis by ketoprofen, acting on cyclooxygenase and lipoxygenase respectively. The formation of bradykinin is also inhibited. Ketoprofen inhibits thrombocyte aggregation.

Pack Sizes: 100 ml and 250 ml.
Outer Packs: 6, 10 and 12 units of 100 ml and 250 ml.

Not all pack sizes may be marketed.

Approved 29 January 2021