

## SUMMARY OF PRODUCT CHARACTERISTICS

### 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]

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One 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

A clear, colourless to yellow solution. Free from visible particles.

### 4. CLINICAL PARTICULARS

#### 4.1. Target species

Cattle, pigs and horses.

#### 4.2. Indications for use, specifying the target species

*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.

#### 4.3. 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.

#### 4.4. Special warnings for each target species

None.

#### **4.5. Special precautions for use**

##### 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.

##### Special precautions to be taken by the person administering the veterinary medicinal product to animals

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.

#### **4.6. Adverse reactions (frequency and seriousness)**

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).

#### **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**

*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.

Not more than 5 ml should be administered at one intramuscular injection site.

The stoppers must not be punctured more than 166 times.

#### **4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary**

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.

#### **4.11. Withdrawal periods**

Cattle, horses, pigs:

Meat and offal: 4 days

Milk (bovine): Zero hours

Not authorised for use in mares 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 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.

#### **5.2. Pharmacokinetic particulars**

After intravenous injection to horses the half-life is approx. 1 hour. The distribution volume is approx. 0.17 l/kg and the clearance approx. 0.3 l/kg. After intramuscular injection to cattle and pigs ketoprofen is quickly absorbed and the maximum plasma concentration of approx. 11 micrograms/ml is obtained within ½ to 1 hour. The mean absorption time is approx. 1 hour. The plasma half-life is 2 – 2 ½ hours.

The bioavailability after intramuscular injection is 90 – 100% in cattle and pigs. In the case of repeated injections at 24 hour intervals ketoprofen exhibits linear and stationary kinetics since the above parameters remain unchanged. Ketoprofen is approx. 95% bound to plasma proteins. Ketoprofen is metabolised mainly by the reduction of the ketone group to a main metabolite. Ketoprofen is quickly excreted; approx. 80% is eliminated within 12 hours after administration. 90% of the elimination takes place via the kidneys, mainly in metabolised form.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1. List of excipients**

L Arginine  
Benzyl alcohol (E1519)  
Citric acid monohydrate (for pH adjustment)  
Nitrogen  
Water for injection

### **6.2. Incompatibilities**

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

### **6.3. Shelflife**

Shelflife of the veterinary medicinal product as packaged for sale: 2 years.  
Shelflife after first opening the immediate packaging: 28 days.

### **6.4. Special precautions for storage**

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

### **6.5. Nature and composition of immediate packaging**

The product is packaged in amber type II glass vials of 100 ml and 250 ml.  
The vials are closed with a type I rubber bromobutyl stopper oversealed with an aluminium cap. Vials are packaged in cardboard boxes containing 1, 6, 10 or 12 units.  
Not all pack sizes may be marketed.

### **6.6. Special precautions for the disposal of unused veterinary medicinal products 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**

Industrial Veterinaria, S.A.  
Esmeralda, 19  
E-08950 Esplugues de Llobregat (Barcelona) Spain  
Tel: +34 934 706 270  
Fax: +34 933 727 556  
e-mail: [invesa@invesa.eu](mailto:invesa@invesa.eu)

## **8. MARKETING AUTHORISATION NUMBER**

**9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

<{DD/MM/YYYY}>

**10. DATE OF REVISION OF THE TEXT**

<{MM/YYYY}>

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

To be supplied only on veterinary prescription

**BOX****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**

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)**

**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[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**

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**

{number}

**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**

{number}

**17. MANUFACTURER’S BATCH NUMBER**

Batch {number}

**PACKAGE LEAFLET FOR:**

**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**

**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 the batch release:

Industrial Veterinaria, S.A.

Esmeralda, 19

08950 Esplugues de Llobregat (Barcelona) Spain

**2. 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

**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 (15mg/kg/day) the recommended dose for 5 days, or to pigs at 3 times (9mg/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**

**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.