SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketosol-100, 100 mg/ml solution for injection for cattle, pigs and horses (EE, BG, HR, LV, RO, SI and SK)
Ketoject, 100 mg/ml solution for injection for cattle, pigs and horses (IT, PL and HU)
Ketoject 100 mg/ml solution for injection for cattle, pigs and horses (CZ)
Ketosol, 100 mg/ml solution for injection for cattle, pigs and horses (CY, DE, EL, ES, FR, IE, LU, NL, PT)
Ketosol vet, 100 mg/ml solution for injection for cattle, pigs and horses (SE)
Ketochemie, 100 mg/ml solution for injection for cattle, pigs and horses (AT, BE, DK, FI)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Ketoprofen.....100.0 mg

Excipients:
Benzyl alcohol (E1519).....10.0 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Clear, slightly yellow solution, free from visible particles.

4. CLINICAL PARTICULARS

4.1. Target species

Cattle, pigs, horses.

4.2. Indications for use, specifying the target species

Cattle:
Diseases associated with inflammation, pain or fever:
- respiratory tract infections.
- mastitis.
- osteoarticular and muscular-skeletal disorders such as lameness, arthritis.
- to ease uprise post parturition.
- injuries.

Where necessary ketoprofen should be combined with appropriate antimicrobial therapy.

Pigs:
Diseases associated with inflammation, pain or fever:

- Postpartum Dysgalactia Syndrome (PPDS) (Mastitis Metritis Agalactia (MMA) syndrome).
- respiratory tract infections.

Where necessary ketoprofen should be combined with appropriate antimicrobial therapy.

Horses:
Diseases affecting the osteoarticular and muscular-skeletal system associated with acute pain and inflammation:

- lameness of traumatic origin.
- arthritis.
- osteitis.
- tendinitis, bursitis.
- navicular syndrome.
- laminitis.
- myositis.

Ketoprofen is also indicated for post-surgical inflammation and symptomatic therapy of colic.

4.3. Contraindications

Do not use in cases of gastro-intestinal ulceration or bleeding.
Do not use in cases of cardiac, hepatic or renal disease.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in cases of blood dyscrasia, coagulopathy or haemorrhagic diathesis.
Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.
Do not use in pigs suffering from PMWS (Post-weaning Multisystemic Wasting Syndrome).

Please also see section 4.7.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

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.
Avoid use in dehydrated, hypovolaemic or hypotensive animals or in animals in a state of shock as there is a potential risk of increased renal toxicity.
Avoid intra-arterial injection.
In absence of safety studies do not use in foals under the age of 15 days.
The recommended dose or duration of treatment should not be exceeded.
Adequate access to drinking water must be ensured at all times.

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

Hypersensitivity reactions (skin rash, urticaria) could occur. People with known hypersensitivity to ketoprofen 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.
The product may cause irritation following skin or eye contact. Avoid splashes on the skin and eyes.
In case of contact with skin, wash thoroughly with soap and water. In case of contact with eyes, rinse thoroughly with water for 15 minutes. If irritation persists seek medical advice.
Wash hands after use.

4.6. Adverse reactions (frequency and seriousness)

In common with all NSAIDs, due to their action of inhibition of prostaglandin synthesis, there can be a possibility in certain individuals of gastric intolerance or impaired renal function.
Allergic reactions may occur very rarely, in this case the treatment should be stopped.
Intramuscular injections may occasionally cause transient irritation.
Repeated administration to pigs may result in reversible inappetence.

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 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).

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.

Pregnancy
Can be used in pregnant cows.
In absence of safety data on pregnant sows, use only according to the benefit/risk assessment by the responsible veterinarian.
Do not use in pregnant mares.

Lactation
Can be used in lactating cows and sows.

4.8. Interaction with other medicinal products and other forms of interaction

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

Ketoprofen is highly bound to plasma proteins and may displace or be displaced by other highly protein bound medicines, such as anticoagulants.
Ketoprofen can inhibit thrombocyte aggregation causing gastrointestinal ulcers and therefore should not be given with drugs with the same adverse reaction profile.

4.9. Amounts to be administered and administration route

Cattle: Intravenous or intramuscular use.
Pigs: Intramuscular use.
Horses: Intravenous use.

Cattle: 3 mg ketoprofen/kg bodyweight (corresponding to 3 ml of product per 100 kg bodyweight), administered by intravenous or deep intramuscular injection once daily for up to 3 consecutive days.

Horses: 2,2 mg ketoprofen/kg bodyweight (corresponding to 1 ml of product per 45 kg bodyweight), administered by intravenous injection once daily for up to 3-5 consecutive days.

In order to treat colic, one injection is normally sufficient. Before each following injection a reassessment of the horse's clinical status is required.

Pigs: 3 mg ketoprofen/kg bodyweight (corresponding to 3 ml of product per 100 kg bodyweight), administered once by deep intramuscular injection.

The rubber stopper can be safely punctured for up to 20 times.

When treating groups of animals (pigs) in one run, use a draw-off needle that has been placed in the vial stopper to avoid excess broaching of the stopper. The draw-off needle should be removed after treatment.

To ensure the correct dosage, bodyweight should be determined as accurately as possible.

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

Overdose can lead to gastro-intestinal ulceration, hepatic and renal impairment. Anorexia, vomiting and diarrhea may occur.
If overdose symptoms are observed, symptomatic treatment should be initiated and it may be necessary to stop treatment with ketoprofen.

4.11. Withdrawal period(s)

Cattle: Meat and offal: 4 days
Milk: zero hours.

Horses: Meat and offal: 4 days.
Not authorized for use in mares producing milk for human consumption.

Pigs: Meat and offal: 4 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Nonsteroidal anti-inflammatory and antirheumatic products, Propionic acid derivatives
ATC vet code: QM01AE03.

5.1. Pharmacodynamic properties

Ketoprofen is a non-steroidal anti-inflammatory drug of the propionic acid class, belonging to the subgroup of carboxylic acid derivatives. Ketoprofen has all three NSAID's specific properties as anti-inflammatory, analgesic and anti-pyretic. The primary pharmacological mechanism of action is based on the inhibition of the prostaglandins synthesis by inhibiting cyclooxygenase pathway of arachidonic acid metabolism.
The formation of bradykinin is inhibited. Ketoprofen inhibits the aggregation of thrombocytes.

5.2. Pharmacokinetic particulars

Ketoprofen is rapidly absorbed. The maximum plasma concentration is reached within 60 minutes after injection. Absolute bioavailability varies between 80 and 95%. Ketoprofen is excreted rapidly, mainly via the urine within 96 hours. The concentration of ketoprofen at the site of inflammation is high and it persists for at least 30-36 hours after a single intravenous injection.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Benzyl alcohol (E1519)
Arginine
Citric acid (for pH adjustment)
Water for injections

6.2. Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other substances in the same syringe.

6.3. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

Storage of the veterinary medicinal product as packaged for sale:

This veterinary medicinal product does not require any special temperature storage conditions.
Store in the original package, protected from light.

Storage after first opening of the immediate packaging:
Do not store above 25 °C.
Store in the original package, protected from light.

6.5. Nature and composition of immediate packaging

Type II amber glass vial closed with bromobutyl rubber stopper and aluminium cap or flip-off cap with aluminium seal and polypropylene cover.

Pack sizes:
Cardboard boxes holding 1 vial of 50 ml or 100 ml.

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

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

7. MARKETING AUTHORISATION HOLDER

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Vanapere tee 14, Püünsi, Viimsi
Harju County 74013
Estonia
Tel.: +372 6 005 005
Fax: +372 6 005 006

8. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally.

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

To be completed nationally.

10. DATE OF REVISION OF THE TEXT

To be completed in accordance with national requirements.

PROHIBITION OF SALE, SUPPLY AND/OR USE

To be completed nationally.