PACKAGE LEAFLET
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)

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:
Interchemie Werken De Adelaar Eesti AS
Vanapere tee 14, Püünsi, Viimsi
Harju County 74013
Estonia

2. 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)
Ketoprofen

Ketoject, 100 mg/ml solution for injection for cattle, pigs and horses (IT, PL and HU)
Ketoprofen

Ketoject 100 mg/ml solution for injection for cattle, pigs and horses (CZ)
Ketoprofen

Ketosol, 100 mg/ml solution for injection for cattle, pigs and horses (CY, DE, EL, ES, FR, IE, LU, NL, PT)
Ketoprofen

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

Ketochemie 100 mg/ml solution for injection for cattle, pigs and horses (AT, BE, DK, FI)
Ketoprofen

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

Each ml contains:
Active substance:
Ketoprofen.....100,0 mg

Excipients:
Benzyl alcohol (E1519).....10,0 mg

Solution for injection.

Clear, slightly yellow solution, free from visible particles.

4. INDICATION(S)

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.

5. 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).

6. ADVERSE REACTIONS

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).

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.

Alternatively, you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle, pigs, horses.

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special temperature storage conditions.
After first opening the immediate packaging do not store above 25 °C.

Store in the original package, protected from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

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.

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.

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.

Lactation:
Can be used in lactating cows and sows.

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.

Overdose (symptoms, emergency procedures, antidotes):
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.

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

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

To be completed nationally.

15. OTHER INFORMATION

Pack sizes:
Cardboard box holding 1 vial of 100 ml.

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