1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Ketoprofen 100.0 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)	10.0 mg
Arginine	
Citric acid (for pH adjustment)	
Water for injections	

Clear, slightly yellow solution, free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs, horses.

3.2 Indications for use for each 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.

If necessary, ketoprofen administration should be combined with appropriate antimicrobial therapy.

Pigs:
Diseases associated with inflammation, pain or fever:
- Postpartum Dysgalactia Syndrome (PPDS) (MMA - Mastitis Metritis Agalactia syndrome).
- respiratory tract infections.

If necessary, ketoprofen administration 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.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
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 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).

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 veterinary medicinal 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 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

Cattle, pigs, horses:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Allergic reaction[1]
Undetermined frequency	Renal insufficiency[2]

(cannot be estimated from the available data)	Injection site irritation[3] Inappetence[4] Gastric irritation[5]

[1] In this case the treatment should be stopped.
[2] Impaired renal function.
[3] Transient, after intramuscular injection.
[4] Reversible, after repeated administration (for pigs only).
[5] Gastric intolerance.

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:
Laboratory studies in rats, mice and rabbits have not produces any evidence of teratogenic or embryotoxic effects. 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.

3.8 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.

3.9 Administration routes and dosage

Cattle: Intravenous (i.v.) or intramuscular (i.m.) use.
Pigs: Intramuscular (i.m.) use.
Horses: Intravenous (i.v.) use.

Cattle: 3 mg ketoprofen per kg bodyweight (corresponding to 3 ml of veterinary medicinal 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 per kg bodyweight (corresponding to 1 ml of veterinary medicinal 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 per kg bodyweight (corresponding to 3 ml of veterinary medicinal 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

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: 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AE03

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

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

5.3 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.
Keep the vial in the outer carton in order to protect from light.

Storage after first opening of the immediate packaging:
Do not store above 25 °C.
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Type II amber glass vial closed with bromobutyl rubber stopper and sealed with an aluminium cap or flip-off cap with polypropylene cover in a cardboard box.

Pack sizes:
Cardboard box with 1 vial of 50 ml solution for injection.
Cardboard box with 1 vial of 100 ml solution for injection.

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

Interchemie Werken De Adelaar Eesti AS

7. MARKETING AUTHORISATION NUMBER(S)

VPA22812/004/001

8. DATE OF FIRST AUTHORISATION

29/04/2022

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

01/12/2025

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).