SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

KETOSAN, 100 mg/ml solution for injection for cattle and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 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.
Clear, slightly yellow solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and pig.

4.2 Indications for use, specifying the target species

Cattle:
The product is indicated for the symptomatic treatment of fever in respiratory infections, as well as analgesic and anti-inflammatory treatment in musculoskeletal ailments and conditions of the udder. In calves, the product can be used to alleviate post-operative pain after dehorning or castration.

Pig:
The product is indicated for antipyretic and anti-inflammatory treatment in diseases of the respiratory system and the mastitis-metritis-agalactia (MMA) syndrome.

4.3 Contraindications

Do not administer in cases of hypersensitivity to ketoprofen or any of the excipients.
Do not administer to animals suffering from gastrointestinal lesions, haemorrhagic diathesis, blood dyscrasia or hepatic, renal or cardiac conditions.

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 of this veterinary medicinal product in old animals or animals younger than 6 weeks has risks. If such use is inevitable, careful clinical monitoring of the animal and lowering the dose may be necessary.
Avoid intra-arterial injection.
Do not exceed the recommended dose or treatment duration.
Use caution when using in dehydrated and hypotensive animals, as there is a potential risk of increased renal toxicity.
Animals should have adequate access to drinking water over the course of treatment.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
People with known hypersensitivity to ketoprofen or benzyl alcohol should avoid contact with the veterinary medicinal product.
This product may cause dizziness and drowsiness. Avoid accidental self-injection and dermal exposure. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. However, do not drive!
This product may cause skin and eye irritation. Avoid contact with skin and eyes. In case of spillage onto skin or eyes, wash the affected area thoroughly with water. If irritation persists, seek medical advice.
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

Repeated intramuscular injections can cause transient irritation.
Ketoprofen can cause gastrointestinal irritation or ulceration due to its mechanism of action (e.g. inhibition of prostaglandin synthesis).
Repeated administration can cause a reversible decrease in appetite in pigs.
Allergic reactions can occur in very rare cases.

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 1000 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 product is safe for use during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not use this veterinary medicinal product in combination with other NSAIDs or with corticosteroids, diuretics, nephrotoxic drugs or anticoagulants.
Do not use in combination with other drugs that could inhibit the aggregation of thrombocytes and cause gastrointestinal ulceration.
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.

4.9 Amount(s) to be administered and administration route

Intramuscular use.

Cattle:
3.0 mg ketoprofen per kg bodyweight, corresponding to 3 ml per 100 kg bodyweight, daily for 1-3 days via intramuscular injection. The maximum volume per injection site in intramuscular injections is 2.6 ml.

Pig:
A single dose of 3.0 mg ketoprofen per kg bodyweight, corresponding to 3 ml per 100 kg bodyweight via intramuscular injection. The maximum volume per injection site in intramuscular injections is 1.7 ml.

The rubber stopper can be safely punctured for up to 15 times. Use of a draw-off needle is recommended when treating large groups of animals. To ensure administration of a correct dosage, body weight should be determined as accurately as possible and dosing devices or syringes with suitable graduations are to be used.

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

An overdose of 5 times the recommended dose is tolerated by cattle. Administration of 3 times the recommended dose for 3 consecutive days is tolerated by pigs.

4.11 Withdrawal periods

Cattle:	Meat and offal:	4 days
	Milk:	zero hours
Pig:	Meat and offal:	5 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group:
Nonsteroidal anti-inflammatory/ antirheumatic drugs (NSAIDs), Anti-inflammatory and Anti-rheumatic products, Non-Steroids, Propionic Acid and Derivatives

ATC vet code: QM01AE03

5.1 Pharmacodynamic properties

Ketoprofen is a nonsteroidal anti-inflammatory drug with anti-inflammatory, analgesic and antipyretic properties. The mechanism of action of ketoprofen is based on interfering with the arachidonic acid derivatives metabolism, leading to inhibition of prostaglandin synthesis. Ketoprofen also interferes with the metabolism of lipoxygenase, which causes inhibition of leukotriene synthesis. Furthermore, ketoprofen is an antagonist to bradykinin.

5.2 Pharmacokinetic particulars

Cattle
In cattle, the blood plasma half-life is approximately 2.5 hours following intramuscular administration, with maximum plasma concentrations being observed after approximately 30 minutes. The bioavailability in cattle is 90-100 %. The excretion of ketoprofen takes place via the urine, with 90% of the administered dose being excreted in 12 hour. Excretion of ketoprofen is completed after 96 hours.

Pig
Following intramuscular injection, ketoprofen is rapidly absorbed. Maximum blood plasma levels are observed after approximately 30 minutes. The excretion of ketoprofen takes place via the urine, with 68% of the administered dose being excreted within 24 hours. Ketoprofen is primarily metabolised by the reduction of the secondary alcohol, which is less pronounced in pigs compared to other species.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal products.

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

Do not refrigerate or freeze.

6.5 Nature and composition of immediate packaging

Amber glass (type II) injection vials of 100 ml closed with a rubber stopper and an aluminium cap in a cardboard box.

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 material derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Interchemie werken “De Adelaar” B.V.
Metaalweg 8
5804 CG Venray
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 48659/4000

9. DATE OF FIRST AUTHORISATION

21 August 2018

10. DATE OF REVISION OF THE TEXT

August 2018

PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only.
To be supplied only on veterinary prescription.

Approved: 21 August 2018