ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Glass injection vials of 100 ml closed with a rubber stopper and an aluminium cap
Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Ketoprofen 100 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle and pig

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTES OF ADMINISTRATION

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.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

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

9. SPECIAL WARNINGS, IF NECESSARY

This product may cause hypersensitive reactions, dizziness and drowsiness. Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 28 days.
Once opened, use by ……

11. SPECIAL STORAGE CONDITIONS

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 material derived from such veterinary medicinal product 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

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

16. MARKETING AUTHORISATION NUMBER

Vm 48659/4000

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Ketosan, 100 mg/ml solution for injection for cattle and pigs

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Manufacturer responsible for batch release:
Interchemie werken “De Adelaar” Eesti AS
Vanapere tee 14, Püünsi village, Viimsi municipality
Harju country 74013
Estonia

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketosan, 100 mg/ml solution for injection for cattle and pigs
Ketoprofen

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:

Active substance:
Ketoprofen 100 mg

Excipients:
Benzyl alcohol (E1519) 10 mg

4. INDICATIONS

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.

5. 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.

6. ADVERSE REACTIONS

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)

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 nation reporting system {national system details}.

7. TARGET SPECIES

Cattle and pig.

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

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.

9. ADVICE ON CORRECT ADMINISTRATION

For intramuscular injection only.

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.

10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.
Keep out of the sight and reach of children.
Shelf-life after first opening the immediate packaging: 28 days.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP:. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special warnings for each target species:
None.

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.

Use during pregnancy, lactation or lay
The product is safe for use during pregnancy and lactation.

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.

Major incompatibilities
Do not mix with any other veterinary medicinal products.

Overdose (symptoms, emergency procedures, antidotes)
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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Package size
100 ml

Prohibition of sale, supply, and/or use
For animal treatment only.
To be supplied only on veterinary prescription.

Approved 19 January 2024