ANNEX I

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 substances:
Ketoprofen 100 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 mg
Arginine	
Citric acid anhydrous (pH adjustment)	
Water for injections	

Clear, slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle and pig.

3.2 Indications for use for each target species

Cattle:
The veterinary medicinal 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 veterinary medicinal product can be used to alleviate post-operative pain after dehorning or castration.

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

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle, pigs:

Very rare (<1 animal / 10 000 animals treated, including isolated reports):	Allergic reaction
Undetermined frequency (cannot be estimated from available data):	Injection site reaction[1] Ulceration[2] Gatrointestinal irritation[2] Appetite loss[3]

[1] Transient, after repeated intramuscular injection

[2] due to its mechanism of action (e.g. inhibition of prostaglandin synthesis).

[3] In pigs, after repeated administration, reversible

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 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

Can be used during pregnancy and lactation.

3.8 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.

3.9 Administration routes and dosage

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.

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

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
Pig:	Meat and offal:	5 days

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code : QM01AE03

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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 hours. 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.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any 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

Do not refrigerate or freeze.

5.4 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.

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” B.V.

7. MARKETING AUTHORISATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

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

TBD

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).

ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketosan, 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:
Ketoprofen 100 mg

3. PACKAGE SIZE

100 ml

4. TARGET SPECIES

Cattle and pig.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal periods:

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

8. EXPIRY DATE

Exp. {mm/yyyy}

Shelf life after first opening the immediate packaging: 28 days.
Once opened use by…

9. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Interchemie werken “De Adelaar” B.V.

14. MARKETING AUTHORISATION NUMBERS

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Glass vial of 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Ketosan, 100 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:
Ketoprofen 100 mg

3. TARGET SPECIES

Cattle and pig.

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal periods:

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

6. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first opening the immediate packaging: 28 days.
Once opened use by…

7. SPECIAL STORAGE PRECAUTIONS

Do not refrigerate or freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Interchemie werken “De Adelaar” B.V.

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:
Ketoprofen 100 mg

Excipients:
Benzyl alcohol (E1519) 10 mg

Clear, slightly yellow solution.

3. Target species

Cattle and pig.

4. Indications for use

Cattle:
The veterinary medicinal 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 veterinary medicinal product can be used to alleviate post-operative pain after dehorning or castration.

Pig:
The veterinary medicinal 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 use in cases of hypersensitivity to the active substance or any of the excipients.
Do not use in 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. Special warnings

Special warnings:

None.

Special precautions for safe use in the target species:

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.

Pregnancy and lactation:

Can be used 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.

Overdose:

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.

Major incompatibilities:

Do not mix with any other veterinary medicinal products.

7. Adverse events

Cattle, pig:

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

(cannot be estimated from available data):	Gatrointestinal irritation[2] Appetite loss[3]

[1] Transient, after repeated intramuscular injection

[2] due to its mechanism of action (e.g. inhibition of prostaglandin synthesis).

[3] In pigs, after repeated administration, reversible

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:

8. Dosage for each species, routes 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 periods

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 precautions for disposal

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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.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Package size
100 ml

15. Date on which the package leaflet was last re vised

TBD

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse events:
Interchemie werken “De Adelaar” B.V.
Metaalweg 8
5804 CG Venray
The Netherlands
Tel: +31 (0)88 5252233
heetika@interchemie.com

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

17. Other information