ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TOLFENAMIC ACID VMD 40 mg/ml solution for injection for cattle, pigs, dogs and cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each mL contains:

Active substance:
Tolfenamic acid..... 40 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)	10.4 mg
Diethylene glycol monoethyl ether	-
Ethanolamine	-
Water for injections	-

Clear, colourless to slightly yellow solution.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs, dogs and cats.

3.2 Indications for use for each target species

Cattle:
As an adjunct in the treatment of pneumonia by improving general conditions and nasal discharge and as an adjunct in the treatment of acute mastitis.

Pigs:
As an adjunct in the treatment of Metritis Mastitis Agalactia syndrome.

Dogs:
Symptomatic treatment of inflammatory and painful conditions of the osteoarticular and musculoskeletal systems.
Reduction of post-surgical pain.

Cats:
Treatment of febrile syndromes.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
In dogs and cats do not use in cases of cardiac, hepatic or acute renal insufficiency, in cases of gastrointestinal ulceration or bleeding, and blood dyscrasia.

3.4 Special warnings

Dogs and cats:
The use of insulin-type needle/syringe is advisable in low-weight animals to ensure an accurate dose.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Do not exceed the recommended dose and duration of treatment.
Use aseptic precautions when administering the product.

Dogs and cats:
The use of the veterinary medicinal product in animals less than 6 weeks of age presents additional risk. If such a use cannot be avoided, animals may require a reduced dosage and careful clinical management is essential.
Avoid use in animals with hypovolaemia due to dehydration or hypotensive animals, as there is a potential risk of increased renal toxicity.
Animals suffering from a chronic renal insufficiency can be treated without requiring an adjustment of the dosage.

Cattle:
When administered intravenously, the product should be injected slowly. At the first signs of intolerance, the injection should be interrupted.

In case of adverse events occurring during the treatment, your veterinarian should be contacted for advice.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle:

Undetermined frequency (cannot be estimated from available data):	Collapse[1]

[1] occasional occurrence following rapid intravenous injection.

Dogs and Cats:

Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea, vomiting
Undetermined frequency (cannot be estimated from available data):	Increase in thirst and/or diuresis[2] Anorexia, presence of blood in faeces

[2] temporary occurrence

In most cases, diarrhoea, vomiting, increase in thirst and/or diuresis disappear spontaneously when treatment is stopped.
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 and lactation:
For dogs and cats, although studies in laboratory animals have not shown any effects on reproduction, use of this product during pregnancy is not recommended.

For cattle and pigs, the veterinary medicinal product can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

Do not administer other NSAIDs concurrently or within 24 hours of each other. Tolfenamic acid is highly bound to plasma proteins and may compete with other highly bound drugs.

3.9 Administration routes and dosage

Cattle: intravenous and intramuscular use
Pigs: intramuscular use
Dogs: intramuscular and subcutaneous use
Cats: subcutaneous use

Cattle:
- For inflammation associated with respiratory disease:
  2 mg of tolfenamic acid/kg bodyweight equivalent to 1 ml of veterinary medicinal product/20 kg bodyweight by intramuscular injection into the neck area. The treatment may be repeated once after 48 hours.
- For use in mastitis:
  4 mg of tolfenamic acid/kg bodyweight equivalent to 1 ml of veterinary medicinal product/10kg bodyweight as a single intravenous injection.

Pigs:
- 2 mg of tolfenamic acid/kg bodyweight equivalent to 1 ml of veterinary medicinal product/20kg bodyweight as a single intramuscular injection.

Cattle and pigs:
Do not exceed 20 ml per injection site.

Dogs:
- Symptomatic treatment of inflammatory and painful conditions of the osteoarticular and musculoskeletal systems:
  4 mg of tolfenamic acid/kg bodyweight administered either as 1 injection of 1 mL of veterinary medicinal product/10 kg bodyweight subcutaneously or intramuscularly which can be repeated 48 hours later with 1 mL of veterinary medicinal product/10 kg bodyweight or 1 injection of 1 mL of veterinary medicinal product/10 kg bodyweight and treatment may be continued orally.
- Reduction of post-surgical pain:
  4 mg of tolfenamic acid/kg bodyweight equivalent to 1 injection of 1 mL of veterinary medicinal product/10 kg bodyweight, by intramuscular route, as premedication, preferably 1 hour before induction of anaesthesia.

Cats:
- Treatment of febrile syndromes:
  4 mg of tolfenamic acid/kg bodyweight administered either as 1 injection of 1 mL of veterinary medicinal product/10 kg bodyweight subcutaneously which can be repeated 48 hours later with 1 mL of veterinary medicinal product/10 kg bodyweight or 1 injection of 1 mL of veterinary medicinal product and treatment may be continued orally.

For multiple vial entry, an aspirating needle or multi-dose syringe is recommended to avoid excessive broaching of the stopper. The stopper of the 25, 50 and 100 mL vials may be punctured up to 20 times. The stopper of the 250 mL vials may be punctured up to 25 times.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In case of overdose, administer symptomatic treatment.

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:
Intramuscular injection:
Meat and offal: 12 days.
Milk: Zero hours.

Intravenous injection:
Meat and offal: 4 days.
Milk: 24 hours.

Pigs:
Meat and offal: 16 days.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AG02

4.2 Pharmacodynamics

Tolfenamic acid (N-(2-methyl-3-chlorophenyl) anthranilic acid) is a non-steroidal anti-inflammatory drug (NSAID) belonging to the fenamate group. Tolfenamic acid exerts anti-inflammatory, analgesic and antipyretic activities.
The anti-inflammatory activity of tolfenamic acid is mainly due to an inhibition of cyclo-oxygenase and thus to a reduction of the synthesis of prostaglandins and thromboxanes, which are important inflammatory mediators.

4.3 Pharmacokinetics

In dogs, tolfenamic acid is rapidly absorbed. By injection, maximum plasma concentrations of about 4 µg/ml (s.c.) and about 3 µg/ml (i.m.) are reached 2 hours after administration of 4 mg of tolfenamic acid/kg (i.m. and s.c.).

In cats, absorption is very rapid. By injection, mean maximum plasma concentration (C_{max}) of about 3.9 µg/ml is reached about 1 hour (T_{max}) after administration of 4 mg of tolfenamic acid/kg.

In cattle and pigs, tolfenamic acid injected by i.m. route at a dose of 2 mg/kg is rapidly absorbed from the injection site with mean maximum plasma concentrations of about 1.4 µg/ml in cattle and 2.3 µg/ml in pigs reached at about 1 hour.

The volume of distribution is about 1.3 l/kg in cattle and pigs.
It is extensively bound to plasma albumin (>97%).

Tolfenamic acid is distributed in all the organs with a high concentration in the plasma, digestive tract, liver, lungs and kidneys. However, the concentration in the brain is low. Tolfenamic acid and its metabolites do not cross the placenta barrier to any great extent.

In cattle and pigs tolfenamic acid distribution involves extracellular fluids where concentrations similar to plasma are achieved both in healthy and inflamed peripheral tissues. It also appears in milk in the active form, mainly associated with the curds.
Tolfenamic acid undergoes extensive enterohepatic recirculation and, as a result prolonged concentrations are found in plasma.

In dogs and cats tolfenamic acid is eliminated mostly unchanged and to a small extent as non-active metabolites.
In dogs with renal insufficiency, the elimination of tolfenamic acid is not affected.

The elimination half-life varies from 3-5 hours in pigs to 8 - 15 hours in cattle.
In cattle and pigs, tolfenamic acid is excreted mainly unchanged in faeces (~30%) and urine (~70%).

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

This veterinary medicinal product does not require any special storage conditions.

5.4 Nature and composition of immediate packaging

Brown, type II glass vials closed with chlorobutyl rubber stoppers with aluminium cap.

Pack sizes:
One vial of 25 mL, 50 mL, 100 mL or 250 mL is packaged per cardboard box.

Not all pack sizes may be marketed.

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

V.M.D.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/329/001–004

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 03/02/2025.

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

{DD/MM/YYYY}

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

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard Box (25 mL, 50 mL, 100 mL, 250 mL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TOLFENAMIC ACID VMD 40 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Tolfenamic acid 40 mg/mL

3. PACKAGE SIZE

25 mL
50 mL
100 mL
250 mL

4. TARGET SPECIES

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Cattle: i.m., i.v.
Pigs: i.m.
Dogs: s.c., i.m.
Cats: s.c.

7. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:
i.m. injection:
Meat and offal: 12 days.
Milk: Zero hours.

i.v. injection:
Meat and offal: 4 days.
Milk: 24 hours.

Pigs:
Meat and offal: 16 days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

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

V.M.D.

14. MARKETING AUTHORISATION NUMBERS

EU/2/24/329/001 (25 mL)
EU/2/24/329/002 (50 mL)
EU/2/24/329/003 (100 mL)
EU/2/24/329/004 (250 mL)

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial (glass - 100 mL and 250 mL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TOLFENAMIC ACID VMD 40 mg/ml solution for injection

2. STATEMENT OF ACTIVE SUBSTANCES

Tolfenamic acid 40 mg/mL

3. TARGET SPECIES

4. ROUTES OF ADMINISTRATION

Cattle: i.m., i.v.
Pigs: i.m.
Dogs: s.c., i.m.
Cats: s.c.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Cattle:
i.m. injection:
Meat and offal: 12 days.
Milk: Zero hours.

i.v. injection:
Meat and offal: 4 days.
Milk: 24 hours.

Pigs:
Meat and offal: 16 days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 28 days.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

V.M.D.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial (glass - 25 mL and 50 mL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

TOLFENAMIC ACID VMD

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Tolfenamic acid 40 mg/mL

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 28 days.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

TOLFENAMIC ACID VMD 40 mg/ml solution for injection for cattle, pigs, dogs and cats

2. Composition

Each ml contains:

Active substance:
Tolfenamic acid: 40 mg

Excipients:
Benzyl alcohol (E1519): 10.4 mg

Clear, colourless to slightly yellow solution.

3. Target species

Cattle, pigs, dogs and cats.

4. Indications for use

Cattle:
As an adjunct in the treatment of pneumonia by improving general conditions and nasal discharge and as an adjunct in the treatment of acute mastitis.

Pigs:
As an adjunct in the treatment of Metritis Mastitis Agalactia syndrome.

Dogs:
Symptomatic treatment of inflammatory and painful conditions of the osteoarticular and musculoskeletal systems.
Reduction of post-surgical pain.

Cats:
Treatment of febrile syndromes.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
In dogs and cats do not use in cases of cardiac, hepatic or acute renal insufficiency, in cases of gastrointestinal ulceration or bleeding, and blood dyscrasia.

6. Special warnings

Special warnings:
Dogs and cats: the use of insulin-type needle/syringe is advisable in low-weight animals to ensure an accurate dose.

Special precautions for safe use in the target species:
Do not exceed the recommended dose and duration of treatment.
Use aseptic precautions when administering the product.

Dogs and cats: The use of the veterinary medicinal product in animals less than 6 weeks of age presents additional risk. If such a use cannot be avoided, animals may require a reduced dosage and careful clinical management is essential.
Avoid use in animals with hypovolaemia due to dehydration or hypotensive animals, as there is a potential risk of increased renal toxicity.
Animals suffering from a chronic renal insufficiency can be treated without requiring an adjustment of the dosage.

Cattle: When administered intravenously, the product should be injected slowly. At the first signs of intolerance, the injection should be interrupted.

In case of undesirable effects occurring during the treatment, your veterinarian should be contacted for advice.

Pregnancy and lactation:
For dogs and cats, although studies in laboratory animals have not shown any effects on reproduction, use of this product during pregnancy is not recommended.
For cattle and pigs, the veterinary medicinal product can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Do not administer other NSAIDs concurrently or within 24 hours of each other. Tolfenamic acid is highly bound to plasma proteins and may compete with other highly bound drugs.

Overdose:
In case of overdose, administer symptomatic treatment.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Cattle:

Undetermined frequency (cannot be estimated from available data):	Collapse[1]

[1] occasional occurrence following rapid intravenous injection.

Dogs and Cats.

Rare (1 to 10 animals / 10,000 animals treated):	Diarrhoea, vomiting
Undetermined frequency (cannot be estimated from available data):	Increase in thirst and/or diuresis[2] Anorexia, presence of blood in faeces

[2] temporary occurrence.

In most cases, diarrhoea, vomiting, increase in thirst and/or diuresis disappear spontaneously when treatment is stopped.

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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

Cattle: intravenous and intramuscular use
Pigs: intramuscular use
Dogs: intramuscular and subcutaneous use
Cats: subcutaneous use

Cattle:

- For inflammation associated with respiratory disease:
  2 mg of tolfenamic acid/kg bodyweight equivalent to 1 ml of veterinary medicinal product/20 kg bodyweight by intramuscular injection into the neck area. The treatment may be repeated once after 48 hours.
- For use in mastitis:
  4 mg of tolfenamic acid/kg bodyweight equivalent to 1ml of veterinary medicinal product/10kg bodyweight as a single intravenous injection.

Pigs:

- 2 mg of tolfenamic acid/kg bodyweight equivalent to 1ml of veterinary medicinal product/20kg bodyweight as a single intramuscular injection.

Cattle and pigs:
Do not exceed 20 ml per injection site.

Dogs:

- Symptomatic treatment of inflammatory and painful conditions of the osteoarticular and musculoskeletal systems:
  4 mg of tolfenamic acid/kg bodyweight administered either as 1 injection of 1 mL of veterinary medicinal product/10 kg bodyweight subcutaneously or intramuscularly which can be repeated 48 hours later with 1 mL of veterinary medicinal product/10 kg bodyweight or 1 injection of 1 mL of veterinary medicinal product/10 kg bodyweight and treatment may be continued orally.
- Reduction of post-surgical pain:
  4 mg of tolfenamic acid/kg bodyweight equivalent to 1 injection of 1 mL of veterinary medicinal product/10 kg bodyweight, by intramuscular route, as premedication, preferably 1 hour before induction of anaesthesia.

Cats:

- Treatment of febrile syndromes:

4 mg of tolfenamic acid/kg bodyweight administered either as 1 injection of 1 mL of veterinary medicinal product/10 kg bodyweight subcutaneously, possibly repeated 48 hours later with1 mL of veterinary medicinal product/10 kg bodyweight or 1 injection of 1 mL of veterinary medicinal product and treatment may be continued orally.

9. Advice on correct administration

For multiple vial entry, an aspirating needle or multi-dose syringe is recommended to avoid excessive broaching of the stopper. The stopper of the 25, 50 and 100 mL vials may be punctured up to 20 times. The stopper of the 250 mL vials may be punctured up to 25 times.

10. Withdrawal periods

Cattle:
Intramuscular injection:
Meat and offal: 12 days.
Milk: Zero hours.

Intravenous injection:
Meat and offal: 4 days.
Milk: 24 hours.

Pigs:
Meat and offal: 16 days.

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

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

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

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.
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

EU/2/24/329/001: Cardboard box with 1 vial of 25 mL
EU/2/24/329/002: Cardboard box with 1 vial of 50 mL
EU/2/24/329/003: Cardboard box with 1 vial of 100 mL
EU/2/24/329/004: Cardboard box with 1 vial of 250 mL

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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:
V.M.D.
HOGE MAUW 900
2370 ARENDONK
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Manufacturer responsible for batch release:
V.M.D.
HOGE MAUW 900
2370 ARENDONK
BELGIUM

LABORATOIRES BIOVE
3, Rue de Lorraine
62510 Arques
FRANCE

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

Local representatives and contact details to report suspected adverse reactions:

België/Belgique/Belgien
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