ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Omeprazole TriviumVet 10 mg gastro-resistant capsules for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gastro-resistant capsule contains:

Active substance:

Omeprazole 10 mg.

Qualitative composition of excipients and other constituents
Lactose monohydrate
Sodium lauril sulfate
Microcrystalline cellulose
Hydroxypropyl cellulose
Mannitol
Disodium phosphate dihydrate
Hypromellose
Talc
Methacrylic acid ethyl acrylate 1:1 copolymer dispersion 30 per cent
Triethyl citrate
Glycerol monostearate 40 – 55
Polysorbate 80
Titanium dioxide
Hard gelatin capsule shell (white/pink)

White/pink hard gelatin capsule filled with white to off-white gastro-resistant coated granules and imprinted with 'TRIV' on white cap and '201O' on pink body with black ink.

3. CLINICAL INFORMATION

3.1 Target species

Dogs.

3.2 Indications for use for each target species

As an aid in the treatment of NSAID-induced gastric ulceration in dogs.

3.3 Contraindications

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

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Dose adjustments (reduced number of capsules) should be considered in dogs with severe liver disease.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The veterinary medicinal product may cause hypersensitivity (allergic) reactions following ingestion or contact with the capsules contents. Adverse gastrointestinal effects and headache may be seen if accidentally ingested, particularly by children.

Contact with contents of the capsule should be avoided, particularly by people with known allergy (hypersensitivity) to omeprazole or one of the excipients.

If the capsule was damaged during administration, wash hands or any exposed skin.

Keep the container tightly closed to prevent accidental access by a child.

In case of accidental ingestion of the product, particularly by a child, or in case of hypersensitivity reactions, seek medical advice if symptoms persist.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Very common (>1 animal / 10 animals treated):	Reduced food intake[1], Weight loss Elevated cholesterol (total)
Common (1 to 10 animals / 100 animals treated):	Diarrhoea, vomiting

[1] Transient and may be observed in the first week of treatment.

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

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects.
The safety of the veterinary medicinal product has not been established in dogs during pregnancy, lactation or in breeding animals. The use of the product is not recommended in such animals.

3.8 Interaction with other medicinal products and other forms of interaction

Omeprazole may delay the elimination of drugs metabolised by liver enzymes (e.g. warfarin, diazepam, cyclosporine).

Decreased gastric acid secretion from treatment with omeprazole may affect the absorption of medicinal products administered via the oral route that require an acidic environment for bioavailability (e.g. ketoconazole, itraconazole, iron, ampicillin esters, cyanocobalamin).

3.9 Administration routes and dosage

Oral use.
Administer the product twice daily at the dose rate of 0.5 to 1 mg omeprazole per kg body weight for a minimum of 14 days.
Treatment duration should be extended until resolution of clinical signs (see also section 4.2) and according to a benefit-risk evaluation by the responsible veterinarian, however, treatment duration should not exceed 8 weeks.
Do not split or open the capsules to ensure adequate bioavailability of the active substance.
Administer the product 30 minutes before feeding.

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

After a 3-5x overdose administered twice daily for up to 79 days, decreased food consumption and body weight, mild hypercholesterolemia, mild thrombocytosis (without other associated signs) and microscopic gastric mucosal changes consisting of degeneration and loss of chief cells with glandular dilation were observed.
Omeprazole has previously been associated with reversible gastric mucosal changes in dog studies.

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

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QA02BC01

4.2 Pharmacodynamics

Omeprazole is a proton pump inhibitor (PPI), it inhibits the H+/K+ proton pump at the luminal surface of the parietal cell that secretes hydrogen ions into the gastric lumen, thus decreasing gastric acid secretion. Reducing the level of acid formation promotes healing of gastric ulcers. After administration of the product at the proposed dose in dogs, mean percentage time gastric pH was at or above 3 and 4 were 95% ± 5% and 92 ± 6% of the day, respectively. In the pivotal dose confirmation study, nine animals (out of a total of 26 animals; 34.6%) were considered a treatment success after two weeks of treatment. In the remainder of the animals, treatment success was attained after 4 weeks of treatment. The therapeutic effect of omeprazole in the treatment of gastric ulcer disease is supported by the well-documented effect gastric acid suppression has on gastric ulcer healing.

4.3 Pharmacokinetics

Omeprazole is rapidly absorbed in all species after oral administration. Omeprazole is a weak base, and therefore is unstable in an acidic environment. It is therefore supplied as a gastro-resistant capsule to prevent inactivation in the stomach and allow absorption in the alkaline environment of the small

intestine. The systemic availability is relatively high in the dog provided the drug is protected from acidic degradation in the stomach. Omeprazole is extensively distributed but primarily in gastric parietal cells. The concentrations achieved at the site of action (the luminal surface of the pump) are significantly higher than those in the blood. Omeprazole undergoes hepatic metabolism by cytochrome P-450 enzymes to inactive metabolites. Omeprazole is excreted as sulphate conjugates in urine after metabolization by hepatic enzymes to inactive metabolites.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

The veterinary medicinal product does not require any special temperature storage conditions.
Keep the bottle tightly closed in order to protect from moisture.
Do not remove desiccant from bottle.

5.4 Nature and composition of immediate packaging

White high-density polyethylene bottle and polypropylene child resistant cap, fitted with a polypropylene heat seal liner and pulpboard wad, in a carton box.
Each bottle contains 30 gastro-resistant capsules.
A 1 g silica gel/activated carbon Tyvek sachet is also included as desiccant.

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

TriviumVet DAC.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/25/336/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 02/04/2025

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

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Omeprazole TriviumVet 10 mg gastro-resistant capsules.

2. STATEMENT OF ACTIVE SUBSTANCES

Each gastro-resistant capsule contains:
Omeprazole 10 mg.

3. PACKAGE SIZE

30 gastro-resistant capsules.

4. TARGET SPECIES

Dogs.

5. INDICATIONS

As an aid in the treatment of NSAID-induced gastric ulceration in dogs.

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the bottle tightly closed in order to protect from moisture.
Do not remove desiccant from bottle.

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

TRIVIUM VET®

14. MARKETING AUTHORISATION NUMBERS

EU/2/25/336/001

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Omeprazole TriviumVet 10 mg gastro-resistant capsules.

2. STATEMENT OF ACTIVE SUBSTANCES

Each gastro-resistant capsule contains Omeprazole 10 mg.

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

7. SPECIAL STORAGE PRECAUTIONS

This veterinary medicinal product does not require any special temperature storage conditions.
Keep the bottle tightly closed in order to protect from moisture.
Do not remove desiccant from bottle.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

TRIVIUM VET®

9. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Omeprazole TriviumVet 10 mg gastro-resistant capsules for dogs

2. Composition

Omeprazole 10 mg.

White / pink hard gelatin capsule filled with white to off-white gastro-resistant coated granules and imprinted with 'TRIV' on white cap and '201O' on pink body with black ink.

3. Target species

Dogs.

4. Indications for use

As an aid in the treatment of NSAID-induced gastric ulceration in dogs.

5. Contraindications

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

6. Special warnings

Special precautions for safe use in the target species:

Dose adjustments (reduced number of capsules) should be considered in dogs with severe liver disease.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

The veterinary medicinal product may cause hypersensitivity (allergic) reactions following ingestion or contact with the capsule's contents. Adverse gastrointestinal effects and headache may be seen if accidentally ingested, particularly by children.
Contact with the contents of the capsule should be avoided, particularly by people with known allergy (hypersensitivity) to omeprazole or one of the excipients.
If the capsule was damaged during administration, wash hands or any exposed skin.
Keep the container tightly closed to prevent accidental access by a child.
In case of accidental ingestion of the product, particularly by a child, or in case of hypersensitivity reactions, seek medical advice if symptoms persist.

Pregnancy, lactation and fertility:

Laboratory studies in rats and rabbits have not produced any evidence of teratogenic effects.

The safety of the veterinary medicinal product has not been established in dogs during pregnancy, lactation or in breeding animals. The use of the product is not recommended in such animals.

Interaction with other medicinal products and other forms of interaction:

Omeprazole may delay the elimination of drugs metabolised by liver enzymes (e.g warfarin, diazepam, cyclosporine).
Decreased gastric acid secretion from treatment with omeprazole may affect the absorption of medicinal products administered via the oral route that require an acidic environment for bioavailability (e.g. ketoconazole, itraconazole, iron, ampicillin esters, cyanocobalamin).

Overdose:
After a 3-5x overdose administered twice daily for up to 79 days, decreased food consumption and body weight, mild hypercholesterolemia, mild thrombocytosis (without other associated signs) and microscopic gastric mucosal changes consisting of degeneration and loss of chief cells with glandular dilation were observed.
Omeprazole has previously been associated with reversible gastric mucosal changes in dog studies.

7. Adverse events

Very common *(>1 animal / 10 animals treated):*	Reduced food intake[1], Weight loss Elevated cholesterol (total)
Common *(1 to 10 animals / 100 animals treated):*	Diarrhoea, vomiting

[1] Transient and may be observed in the first week of treatment.

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} https://www.ema.europa.eu/documents/template-form/qrd-appendix-i-adverse-event-phv-mss-reporting-details_en.docx.

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

Oral use.
Administer the product twice daily at the dose rate of 0.5 to 1 mg omeprazole per kg body weight for a minimum of 14 days.
Treatment duration should be extended until resolution of clinical signs and according to a benefit-risk evaluation by the responsible veterinarian, however, treatment duration should not exceed 8 weeks.
Do not split or open the capsules to ensure adequate bioavailability of the active substance.

9. Advice on correct administration

Administer the product 30 minutes before feeding.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
The veterinary medicinal product does not require any special temperature storage conditions.
Keep the bottle tightly closed in order to protect from moisture.
Do not remove desiccant from bottle.
Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

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/2/25/336/001 - 30 capsules.

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 and contact details to report suspected adverse events:
TriviumVet DAC
Unit 1N, Block 1A
Cleaboy Business Park
Old Kilmeaden Road
Waterford
X91 DEC4
Ireland
Email: PV@triviumvet.com
Phone: +353 85 262 3080

Manufacturer responsible for batch release:
Acorn Regulatory Consultancy Services
Suite 6, Powerstown House
Gurtnafleur Business Part

Clonmel
Co. Tipperary
E21 R766
Ireland