

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zetbelis 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 laurilsulfate
Microcrystalline cellulose
Hydroxypropylcellulose
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 '2010' 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

In a laboratory 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. Alongside the veterinary medicinal product, animals enrolled in this study were also treated with antiemetics, antimicrobials, intravenous fluid therapy, and/or opioid analgesics.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Due to the quantitative composition of the veterinary medicinal product and the recommended dose (see also section 3.9 Administration routes and dosage), it is only authorised for administration to dogs with a bodyweight of at least 10 kg.

Due to reports of the development of hypergastrinaemia in other mammalian species following prolonged treatment with omeprazole, treatment with the veterinary medicinal product should not exceed 8 weeks.

Omeprazole is metabolised by the hepatic microsomal cytochrome system. Therefore, severe hepatic dysfunction may be associated with increases in the systemic availability and a prolonged duration of effect of the veterinary medicinal product. Based on the benefit-risk evaluation by the responsible veterinarian, dose adjustments (i.e., a reduced number of capsules) should therefore 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. People with a known hypersensitivity to omeprazole or the excipient, mannitol should administer the veterinary medicinal product with caution.

Adverse gastrointestinal effects and headache may be seen if accidentally ingested, particularly by children.

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.

Exposure to the contents of capsules may cause skin, eye, and/or respiratory irritation. Contact with the contents of the capsule should be avoided.
If the capsule is damaged during administration, wash hands or any exposed skin.

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, mycophenolate, clopidogrel, digoxin).

3.9 Administration routes and dosage

Oral use.

To ensure a correct dosage, body weight should be determined as accurately as possible.

To achieve the recommended dose, dogs must be at least 10 kg in bodyweight (see also section 3.5 Special precautions for safe use in the target species).

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 (see also section 3.5 Special precautions for safe use in the target species).

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. 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 mammalian species studied to date after oral administration. Omeprazole is a weak base and is therefore unstable in an acidic environment.

The veterinary medicinal product is therefore supplied as a gastro-resistant formulation 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 to 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 metabolisation 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 product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

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 Designated Activity Company

7. MARKETING AUTHORISATION NUMBER

Vm 60798/5000

8. DATE OF FIRST AUTHORISATION

31 March 2026

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

March 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 09 April 2026