

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON BOX)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Zetbelis 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**



**14. MARKETING AUTHORISATION NUMBER**

Vm 60798/5000

**15. BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING  
UNITS (BOTTLE LABEL)**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Zetbelis



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES**

Omeprazole 10 mg.

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

<Exp. {mm/yyyy}>

**PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:**

**PACKAGE LEAFLET**

**1. Name of the veterinary medicinal product**

Zetbelis 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 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.

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

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, mycophenolate, clopidogrel, digoxin.)

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

<i>Very common (&gt;1 animal / 10 animals treated):</i>	Reduced food intake <sup>1</sup> , Weight loss Elevated cholesterol (total)
<i>Common (1 to 10 animals / 100 animals treated):</i>	Diarrhoea, vomiting
<sup>1</sup> <i>Transient and may be observed in the first week of treatment.</i>	

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 at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: [adverse.events@vmd.gov.uk](mailto:adverse.events@vmd.gov.uk)

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

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 6 Special Warnings).

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 (see section 6 Special Warnings).

## 9. Advice on correct administration

Do not split or open the capsules to ensure adequate bioavailability of the active substance.

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.

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**

Vm 60798/5000

<Not all pack sizes may be marketed.>

## **15. PID LINK (Do not print heading)**

*[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]*

Find more product information by searching for the 'Product Information Database' on [www.gov.uk](http://www.gov.uk).

## **16. Contact details**

Marketing authorisation holder and contact details to report suspected adverse reactions:

Triviumvet Designated Activity Company  
Unit 3A, Cleaboy Business Park  
Old Kilmeaden Road  
Waterford  
X91 H5FE  
Ireland

Email: [PV@triviumvet.com](mailto:PV@triviumvet.com)  
Phone: +353 85 262 3080

Manufacturer responsible for batch release:

APL Swift Services (Malta Ltd.)  
HF26, Industrial Estate Hal Far  
Birzebbugia  
BBG3000  
Malta

**17. Other information**

POM-V

*Gavin Hall*  
Approved: 23 April 2026