



NAME OF THE VETERINARY MEDICINAL PRODUCT

Rx Gastroplex® Omeprazol 5 mg

2. PHARMACEUTICAL PRESENTATION

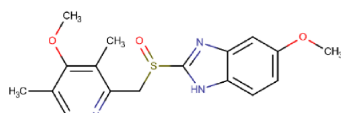
Tablets.

3. FORMULA

Each tablet contains:

Omeprazole	5 mg
Excipient q.s.	1 tablet

4. STRUCTURAL FORMULA



5. THERAPEUTIC INDICATIONS

Proton pump inhibitor; an aid in the short- and long-term treatment and prevention of symptoms related to acid-peptic disorders: esophagitis, erosive gastritis, gastric ulcers, and duodenal ulcers (Cui *et al.*, 2020; Papich 2021).

6. SPECIES

Canine and feline (Allerton, 2020; Bruyette, 2020).

7. APPLICATION METHOD

Oral (Allerton, 2020; Bruyette, 2020; Moot *et al.*, 2019; Papich, 2021).

8. DOSAGE

General dosage:

1.0 mg per kg (2.2 lb) of body weight every 12 or 24 h. (Bruyette, 2020; Drobacz *et al.*, 2019; Moot *et al.*, 2019; Papich, 2021).

Rx Gastroplex® Omeprazol 5 mg

1 tablet per 5 kg (11 lbs) of body weight (equivalent to 5 mg of omeprazole per 5 kg (11 lbs) of body weight) every 12 or 24 h, for a maximum of 8 weeks (Allerton, 2020; Bruyette, 2020; Drobacz *et al.*, 2019; Moot *et al.*, 2019; Papich, 2021).

In infections caused by *Helicobacter pylori*, **Rx Gastroplex® Omeprazol 5 mg** can be administered in combination with metronidazole or amoxicillin, as indicated by the Veterinarian (Greene, 2012; Papich, 2021).

The dosage may be adjusted at the discretion of the Veterinarian.

9. MECHANISM OF ACTION

Omeprazole is the most widely used proton pump inhibitor (PPI) in animals. This drug inhibits gastric acid secretion by inhibiting the K⁺/H⁺ pump (potassium pump). Omeprazole is more potent and longer acting than histamine H2 antagonists and is associated with better efficacy (Papich, 2021; Plumb, 2018).

10. PHARMACOKINETICS

Since omeprazole is a weak base, it is unstable in acidic environments. Therefore, its commercial formulation must include an enteric coating to prevent degradation by the stomach's acidic pH before it is absorbed in the small intestine. Once absorbed, omeprazole is distributed throughout the body and concentrates in the gastric parietal cells. From there, it diffuses into the secretory canals, where the drug becomes protonated, activating and exerting its effect. Omeprazole is extensively metabolized in the liver into at least six different metabolites, which are excreted primarily in the urine and also through bile in the feces. The pharmacokinetic parameters reported in dogs are as follows: bioavailability of 35 to 60%, volume of distribution of 0.3 to 0.4 L/kg, and elimination half-life of 0.75 hours (Merton, 2012; Sumano, 2015).

11. WARNINGS

Do not administer in patients with hypersensitivity to the drug. In patients with renal or hepatic disease, adjust the dosage accordingly (Marín, 2015).

Do not exceed the recommended dose and time of treatment (Allerton, 2020; Plumb, 2018).

12. ADVERSE REACTIONS

Gastrointestinal distress (anorexia, colic, nausea, vomiting, diarrhea and constipation) has been reported sporadically (Allerton, 2020; Plumb, 2018).

13. OVERDOSAGE

Omeprazole is considered to have low toxicity, as the oral LD50 in rats is >4 g/kg (2.2 lb) of body weight (Plumb, 2018; Sumano, 2015). (Note: Conversion is based on 1 kg = 2.20462 lbs.)

14. DRUG-DRUG INTERACTIONS

Omeprazole can prolong the half-life of diazepam and cyclosporine by interfering with their metabolism, since it inhibits hepatic P-450 enzymes. Plasma concentrations of omeprazole and clarithromycin increase during their concurrent administration. Omeprazole reduces the absorption of drugs that require an acidic pH, such as ketoconazole (Marín, 2015; Papich, 2021; Plumb, 2018).

15. INTERACTIONS WITH LABORATORY TESTS

Omeprazole may cause an increase in liver enzymes, and at the start of its administration, it can lead to elevated serum gastrin levels (Papich, 2016; Plumb, 2018).

16. USE DURING GESTATION AND/OR NURSING

No studies have been conducted to establish the safety of omeprazole in pregnant or lactating canines (Plumb, 2018).

17. PRECAUTIONS

Store in a cool, dry place away from direct sunlight and/or heat.

Keep out of reach of children and pets. Product for exclusive use in Veterinary Medicine.

18. EXPIRATION PERIOD

Expiration Period of the veterinary drug product as packaged for sale: 24 months.

19. HOLDER OF THE REGISTRY

HOLLAND DE MEXICO SA DE CV
Calle 21 Este. No 12, Col. Civac
Jiutepec, Morelos, CP 62578

20. REGISTRATION NUMBER

Q-4196-276.

21. PROHIBITION OF SALE, DISTRIBUTION AND/OR USE

Consult your veterinarian.

Prescription required.

22. PRESENTATION

Box with 30 tablets.

23. REFERENCES

- 23.1 Allerton F. BSAVA Small Animal Formulary. 10 th ed., Part A: Canine and Feline. 10 th ed., UK, 2020.
- 23.2 Bruyette D. Clinical Small Animal International Medicine. Vol 1. Wiley Blackwell, 1st ed., India, 2020.
- 23.3 Cui *et al.* Factors Contributing to Drug Release From Enteric-Coated Omeprazole Capsules: An In Vitro and In Vivo Pharmacokinetic Study and IVIVC Evaluation in Beagle Dogs. Dose-Response: An International Journal 2020; 1 -13. 22.4 Drobatz *et al.* Textbook of Small Animal Emergency Medicine. Vol. 1. Wiley-Blackwell, India, 2019.
- 23.5 Greene, C. Infectious Diseases of the dog and cat. 4th ed., Elsevier Saunders, USA, 2012.
- 23.6 Marin H. Practical Pharmacology in cats. 1 ed., Mexico, 2015.
- 23.7 Merton B. Small Animal Clinical Pharmacology and Therapeutics. 2nd ed. Elsevier, 2012.
- 23.8 Moot *et al.* Blackwell's Five Minute Veterinary Consult Clinical Companion. Wiley-Blackwell, India, 2019.
- 23.9 Papich M. Papich Handbook of Veterinary Drugs. 5th ed., Elsevier, China, 2021.
- 23.10 Plumb, D. Veterinary Drug Handbook. Ninth Edition, Blackwell Publishing, Iowa, 2018.
- 23.11 Sumano *et al.* Veterinary Pharmacology, 4 ed. Aranda, 2015.