

NAME OF THE VETERINARY MEDICINAL PRODUCT

Rx Spectrum® Rifaximina

2. PHARMACEUTICAL PRESENTATION

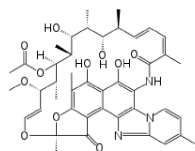
Powder for oral suspension

3. FORMULA

Once reconstituted, each 100 ml contains:

Rifaximin	3.4 g
Vehicle q.s.	100 ml

4. STRUCTURAL FORMULA



5. THERAPEUTIC INDICATIONS

Treatment for gastrointestinal infections caused by bacteria susceptible to rifaximin such as: *Escherichia coli*, *Enterobacter* sp., *Proteus* sp., *Clostridium* sp. among others. Adjunct treatment for inflammatory bowel disease (IBD) and hepatic encephalopathy (Aquino *et al.*, 2022; Grene, 2012; Menozzi *et al.*, 2016).

6. SPECTRUM

Rifaximin is a broad spectrum antimicrobial, active against gram positive and gram negative bacteria, both aerobic and anaerobic, however, its oral effect is focused on:

- **Gram-negative aerobes:**
Enterotoxigenic *Escherichia coli* (ETEC), *Enterobacter* sp., *Proteus* sp., *Pseudomonas* sp., *Klebsiella* sp., *Enterobacter* sp.
- **Gram-positive aerobes:**
Enterococcus sp., *Streptococcus* sp., *Staphylococcus* sp.
- **Gram-positive anaerobes:**
Clostridium sp., *Peptostreptococcus* sp.
- **Gram-negative anaerobes:**
Bacteroides sp., *Fusobacterium* sp.

(Adachi *et al.*, 2006; Calanni *et al.*, 2014; Gobernado *et al.*, 2004; Huhulescu *et al.*, 2011; Koo *et al.*, 2010).

7. SPECIES

Canine and feline.

8. APPLICATION METHOD

Oral.

9. DOSAGE

General dosage:

Gastrointestinal infections: 17 mg/kg (2.2 lb) of body weight every 8 hours for 4 days (Aquino *et al.*, 2021).

Inflammatory bowel disease: 25 mg/kg (2.2 lb) every 12 hours for 21 days (Menozzi *et al.*, 2016).

Hepatoencephalopathy: 550 mg per patient every 12 or 24 h. (Grene, 2012).

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Canine and feline species:

Gastrointestinal infections: 2.5 ml per 5 kg (11 lbs) of body weight equivalent to 85 mg/5 kg or (11 lbs) every 8 hours for 4 days. Inflammatory bowel disease: 3.7 ml per 5 kg (11 lbs) of body weight equivalent to 125.8 mg/5 kg (11 lbs) every 12 hours for 21 days.

Hepatoencephalopathy: 16 ml per patient (equivalent to 550 mg per patient) every 12 or 24 h.

(Aquino *et al.*, 2022; Grene, 2012; Menozzi *et al.*, 2016).

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

10. MECHANISM OF ACTION

Rifaximin exerts its antibacterial activity by binding to the β -subunit of bacterial DNA-dependent RNA polymerase, thereby inhibiting bacterial RNA synthesis (Calanni *et al.*, 2014).

11. PHARMACOKINETICS

Rifaximin is an orally administered, virtually non-absorbable antibiotic that acts locally in the gastrointestinal tract. Less than 0.01% of the dose is detectable in plasma, and 97% is recovered unchanged in the feces (Bennet *et al.* 2020; Rivkin *et al.*, 2011).

12. WARNINGS

Do not administer in patients with fever, bloody diarrhea or hypersensitivity to rifaximin or other antimicrobial agents of the rifamycin family (Adachi *et al.*, 2006; Bylund *et al.*, 2009).

Do not administer in patients with evidence of severe intestinal ulcerative lesions or obstruction (Ladevaia *et al.*, 2011).

Once reconstituted, keep refrigerated for a maximum of 16 days, after this time the product should be discarded. Incorrect use of this product may cause bacterial resistance.

13. ADVERSE REACTIONS

Rifaximin rarely causes side effects, with vomiting being the most common (Ojetti *et al.*, 2009).

14. OVERDOSAGE

In studies with laboratory rats, at doses of 2000 mg/kg (2.2 lb), only neuronal excitation was observed (Ojetti *et al.*, 2009).

15. DRUG-DRUG INTERACTIONS

Due to its minimal absorption, it does not affect the metabolism of other drugs. In a study conducted on rats treated with rifaximin for 6 months, no significant induction of hepatic drug metabolism was observed. (Ojetti *et al.*, 2009).

16. INTERACTIONS WITH LABORATORY TESTS

No reports were found on the effect of rifaximin in laboratory tests.

17. USE DURING GESTATION AND/OR NURSING

No information was reported on its safety during pregnancy or lactation in dogs and cats.

18. 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.

19. EXPIRATION PERIOD

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

20. HOLDER OF THE REGISTRY

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

21. REGISTRATION NUMBER

Q-4196-266

22. PROHIBITION OF SALE, DISTRIBUTION AND/OR USE

Prescription required.

Consult your veterinarian.

Shake before use.

23. PRESENTATION

Box with bottle/powder for suspension 60 mL (2.02 fl oz).

24. REFERENCES

24.1 Adachi *et al.*, Rifaximin: A Novel Nonabsorbed Rifamycin for Gastrointestinal Disorders. Reviews of Anti-Infective Agents, 2006; 42: 541-547

24.2 Aquino *et al.* Clinical efficacy of rifaximin in the management of infectious diarrhea in dogs and cats. Dept. Physiology and Pharmacology, FMVZ, UNAM, 2021.

24.3 Bennet *et al.* Principles and Practice of Infectious Diseases. 9th ed., Elsevier, 2020.

24.4 Bylund *et al.* xPharm: The Comprehensive Pharmacology. Elsevier, 2008.

24.5 Calanni *et al.* Rifaximin: beyond the traditional antibiotic activity. The Journal of Antibiotics 2014; 67:667-670.

24.6 Greene, C. Infectious Diseases of the dog and cat. Fourth edition, Elsevier, 2012.

24.7 Gobernado *et al.* Review, Rifaximin. Rev Esp Quimioterap, 2004; 17 (2): 141-153

24.8 Huhulescu *et al.* Rifaximin disc diffusion test for in vitro susceptibility testing of Clostridium difficile. Journal of Medical Microbiology 2011; 60:1206-1212.

24.9 Koo *et al.* Rifaximin: A Unique Gastrointestinal-Selective Antibiotic for Enteric Diseases. Curr Opin Gastroenterol 2010; 26(1): 17-25.

24.10 Ladevaia *et al.* Rifaximin in the treatment of hepatic encephalopathy. Hepatic Medicine: Evidence and Research 2011;3 109-117.

24.11 Menozzi *et al.* Rifaximin is an effective alternative to metronidazole for the treatment of chronic enteropathy in dogs: a randomised trial. BMC Veterinary Research 2016; 12 (217): 1-9.

24.12 Ojetti *et al.* Rifaximin pharmacology and clinical implications. Expert Opin Drug Metab Toxicol 2009; 5(6): 675-682.

24.13 Rivkin *et al.* Rifaximin: New Therapeutic Indication and Future Directions. Clinical Therapeutics 2011; 33:821-827.