



1. VETERINARY MEDICATION NAME

Rx Spectrum® Clindamicina 50 mg

2. PHARMACEUTICAL PRESENTATION

Tablets

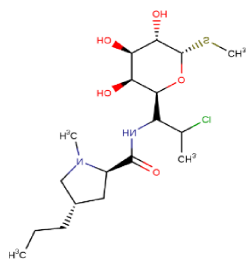
3. FORMULA

Each tablet contains:

Clindamycin hydrochloride 50 mg

Excipient q.s. 1 tablet

4. STRUCTURAL FORMULA



5. THERAPEUTIC INDICATIONS

Treatment of oral infections, skin infections (bacterial dermatitis), abscesses, infected wounds and osteomyelitis caused by bacteria susceptible to clindamycin. Due to its antiprotozoal action, it can be administered for the treatment of toxoplasmosis and babesiosis. Useful for treating animals allergic to penicillin (Plumb, 2018).

6. SPECTRUM

Its spectrum includes most gram-positive cocci, including *Staphylococcus* sp., *Streptococcus* sp. (except *S. faecalis*). Other susceptible microorganisms are: *Corynebacterium* spp., *Nocardia asteroides*, *Erysipelothrix* spp., and *Mycoplasma* spp. Susceptible anaerobic bacteria are: *Bacteroides* spp., *Fusobacterium* spp., *Clostridium perfringens*, *C. tetani*, *Actinomyces* spp., *Peptostreptococcus* spp. and *Peptococcus* spp. It also shows activity against *Toxoplasma gondii* and *Babesia* spp. (Plumb, 2018).

7. SPECIES

Canines (Plumb, 2018).

8. ADMINISTRATION ROUTE

Oral.

9. DOSAGE

General dosage:

5 to 10 mg per kg (2.2 lb) body weight, every 12 h, or double the dose every 24 h, for a period of 7 to 14 days (Norsworthy *et al.*, 2011; Plumb, 2018; Sumano 2015).

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Canines: 1 tablet (50 mg) per 10 kg (22 lbs) of body weight every 12 hours, for 7 to 14 days, or 2 tablets (100 mg) per 10 kg (22 lbs) of body weight every 24 hours, for 7 to 14 days.

In cases of osteomyelitis, it is recommended to double the dose of the tablets or solution and extend the treatment for up to 28 days.

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

10. MECHANISM OF ACTION

It may act as either a bacteriostatic or bactericidal agent, depending on the drug concentration at the site of infection and the susceptibility of the microorganism. Lincosamides act by binding to the 50S ribosomal subunit of susceptible bacteria, inhibiting the formation of peptide bonds (Merton, 2012; Riviere, 2018).

11. PHARMACOKINETICS

In dogs, oral bioavailability is approximately 73%, and the elimination half-life ranges from 2 to 5 hours following oral administration. The volume of distribution is 0.9 L/kg (approximately 0.41 gal/2.2 lb). Food decreases its rate of absorption but does not inhibit it. Peak serum levels are reached approximately 45 to 60 minutes after oral dosing. Clindamycin is distributed throughout most tissues. Therapeutic levels are achieved in bone, synovial fluid, bile, pleural fluid, peritoneal fluid, skin and cardiac muscle. Clindamycin also penetrates well into abscesses. Clindamycin is approximately 93% bound to plasma proteins, crosses the placenta and can be distributed in milk at concentrations equal to those of plasma. It is partially metabolized in the liver into active and inactive metabolites. The drug and metabolites are excreted in urine, feces and bile. The half-life may be prolonged in patients with severe renal or hepatic dysfunction (Plumb, 2018).

12. WARNINGS

Clindamycin is contraindicated in patients with known hypersensitivity to clindamycin or lincomycin (Sumano, 2015). Incorrect use of this product may cause bacterial resistance.

13. ADVERSE REACTIONS

It has been reported that oral clindamycin can cause gastroenteritis, emesis, loose stools and sporadic hemorrhagic diarrhea in dogs. Cats present salivation with the administration of the oral solution. There are reports of esophageal injury in cats.

In dogs and cats, the most serious side effect observed in humans—pseudomembranous colitis caused by the overgrowth of *Clostridium difficile*—has not been reported (Plumb, 2018).

14. OVERDOSAGE

In dogs, oral administration of up to 300 mg/kg (136 mg/lb) of body weight per day for one year did not produce toxicity. However, when administered at 600 mg/kg (272 mg/lb) per day, anorexia, vomiting, and weight loss were observed (Plumb, 2018).

15. DRUG INTERACTIONS

Clindamycin can reduce cyclosporine levels.

Clindamycin and erythromycin have been shown to be antagonistic.

Clindamycin can produce neuromuscular blockades, so it is not recommended to be administered together with drugs that have similar or equal activity (p. e.g., pancuronium), because they can increase the intensity in their effect (Plumb, 2018).

16. INTERACTIONS WITH LABORATORY TESTS

It may generate a slight increase in indicative liver function values (AST, ALT and alkaline phosphatase), without data of clinical significance (Plumb, 2018).

17. USE DURING PREGNANCY AND/OR LACTATION

It has not been implicated in teratogenic effects, since there are no reports of adverse effects in laboratory animals. If infants receive milk from mothers who have received clindamycin they may develop diarrhea due to an imbalance in their gastrointestinal flora (Plumb, 2018).

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

Shelf life of the veterinary medicinal 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-4196-142

22. SALE, DISPENSATION, AND/OR USE PROHIBITION

Prescription required.

Consult your veterinarian.

23. PRESENTATION

Box with 20 tablets.

24. REFERENCES

- 24.1 Merton B. Small Animal Clinical Pharmacology & Therapeutics. Second edition, Elsevier, 2012.
- 24.2 Norsworthy *et al.* The Feline Patient, Fourth Edition, Wiley-Blackwell, Singapore, 2011.
- 24.3 Plumb, D. Veterinary Drug Handbook. Ninth Edition, Blackwell Publishing, Iowa, 2018.
- 24.4 Riviere *et al.* Veterinary Pharmacology and Therapeutics. Tenth Edition, Willey Blackwell, India, 2018.
- 24.5 Sumano *et al.* Veterinary Pharmacology. 4th ed. Mexico, 2015.

CERTIFICATE OF ACCURACY

I, the undersigned, Diana Alicia de Regules Silva, Certified Translator No. P037-2020 SPANISH-ENGLISH-SPANISH, duly sworn and authorized by the Mexican Supreme Court of Justice, as per the Federal Judiciary Council's publication in the Federal Official Gazette on December 11, 2024 (accessible at https://www.dof.gob.mx/2024/CJF/listado_peritos_PJF_2025.pdf page 204):

1. I hereby certify that I have translated a **2**-page document in Spanish, titled **"FICHA TÉCNICA"** into a **2**-page English document, titled **"TECHNICAL DATA SHEET"** both of which are attached herewith.



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