

NAME OF THE VETERINARY MEDICINAL PRODUCT

Rx Spectrum® Clindamicina

2. PHARMACEUTICAL PRESENTATION

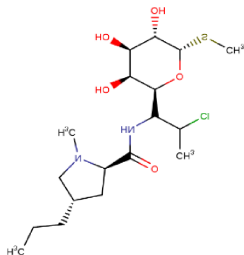
Oral solution

3. FORMULA

Each ml contain:

Clindamycin hydrochloride	25 mg
Vehicle q.s.	1 ml

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* sp., *Nocardia asteroides*, *Erysipelothrix* sp., and *Mycoplasma* sp. Susceptible anaerobic bacteria are: *Bacteroides* sp., *Fusobacterium* sp., *Clostridium perfringens*, *C. tetani*, *Actinomyces* sp., *Peptostreptococcus* sp. and *Peptococcus* sp. It also has activity against *Toxoplasma gondii* and *Babesia* sp. (Plumb, 2018).

7. SPECIES

Canine and Feline (Plumb, 2018).

8. APPLICATION METHOD

Oral.

9. DOSAGE

General dosage:

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

Rx Spectrum® Clindamicina oral solution

Canines and felines: 1 ml (25 mg) per 5 kg (11 lb.) of body weight every 12 hours, for 7 to 14 days, or 2 ml (50 mg) per 5 kg of body weight (11 lb.) every 24 hours, for 7 to 14 days.

In cases of osteomyelitis, it is recommended to double the dose of the tablets or oral solution and extend the treatment for up to 28 days to ensure effective management. The dosage may be adjusted at the discretion of the Veterinarian.

10. MECHANISM OF ACTION

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

11. PHARMACOKINETICS

In dogs, the oral bioavailability is approximately 73%, and the elimination half-life is 2 to 5 hours after oral administration. The volume of distribution is 0.9 L/kg (2.2 lb). Food decreases the rate of absorption, but does not inhibit it. Maximum serum levels are reached approximately 45 to 60 minutes after oral dosing. Clindamycin is distributed in 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 into breast milk at concentrations similar to those in 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, vomiting, soft stools, and occasionally hemorrhagic diarrhea in dogs. Cats present salivation with the administration of the oral solution. There are case reports of esophageal damage in cats.

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

14. OVERDOSAGE

In dogs, the oral administration of up to 300 mg per kg of body weight per day (2.2 lb) of body weight per day for one year did not produce toxicity. However, when administered 600 mg per kg of body weight per day (2.2 lb.) of body weight per day, anorexia, vomiting, and weight loss were observed (Plumb, 2018).

15. DRUG-DRUG INTERACTIONS

Clindamycin can reduce cyclosporine levels.

Clindamycin and erythromycin have been shown to be antagonistic.

Clindamycin can cause neuromuscular blockade, so it is not recommended to administer it with drugs that have similar or identical activity (e.g., pancuronium), as they may intensify its effect (Plumb, 2018).

16. INTERACTIONS WITH LABORATORY TESTS

It may cause a slight increase in values indicative of liver function (AST, ALT, and alkaline phosphatase), without any clinically significant data (Plumb, 2018).

17. USE DURING GESTATION AND/OR NURSING

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

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-4196-217

22. PROHIBITION OF SALE, DISTRIBUTION AND/OR USE

Prescription required.

Consult your veterinarian.

Shake before use.

23. PRESENTATION

Box with bottle suspension 25 mL (0.84 fl oz).

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, Wiley Blackwell, India, 2018.
- 24.5 Sumano *et al.* Farmacología Veterinaria. Fourth 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 "**ft clindamicina sol**," into a 2-page English document, titled "**ft clindamicina sol**", both of which are attached herewith.



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