

**HOLLAND**
DE MÉXICO**TECHNICAL
DATA
SHEET****Antimicrobials****1. VETERINARY MEDICATION NAME**

Rx Spectrum® Doxyciclina 50 mg

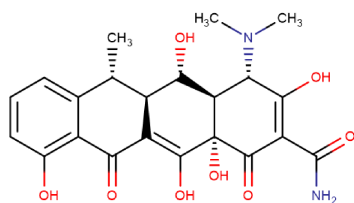
2. PHARMACEUTICAL PRESENTATION

Tablets

3. FORMULA

Each tablet contains:

Doxycycline hyclate	50 mg
Excipient q.s.	1 tablet

4. STRUCTURAL FORMULA**5. THERAPEUTIC INDICATIONS**

Treatment of infections caused by microorganisms susceptible to doxycycline, particularly respiratory (pneumonias, bronchopneumonias, kennel cough, feline respiratory disease, pharyngitis, tracheitis, bronchitis, and sinusitis), dermatological (otitis, abscesses, and cellulitis), articular, genitourinary, intestinal (gastroenteritis), leptospirosis, anaplasmosis, ehrlichiosis, and brucellosis.

6. SPECTRUM

It is active against a broad spectrum of gram-positive and gram-negative bacteria, anaerobic bacteria, and other microorganisms including *Leptospira* spp., *Anaplasma* spp. and *Ehrlichia* spp. (Plumb, 2008).

7. SPECIES

Canines and felines (Papich, 2014).

8. ADMINISTRATION ROUTE

Oral (Papich, 2014).

9. DOSAGE**General dosage:**

10 mg per kg (2.2 lb) body weight, every 24 h., for a minimum period of 7 days and can be prolonged in chronic cases depending on the condition (Papich, 2014).

Rx Spectrum® Doxyciclina 50 mg

Canines and felines: 1 tablet for each 5 kg (11 lb) of body weight every 24 hours.

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

10. MECHANISM OF ACTION

Doxycycline binds to the 30S ribosomal subunit, inhibiting bacterial growth by interfering with the binding of aminoacyl-tRNA to the receptor site on the mRNA complex, thereby preventing the incorporation of amino acids into the growing peptide chain. Tetracyclines are also believed to reversibly bind to the 50S ribosomal subunit and alter the cytoplasmic membrane permeability in susceptible organisms. In some microorganisms, it has a bacteriostatic effect, while in others it exerts a bactericidal effect when administered at higher doses (Sumano *et al.*, 2015).

11. PHARMACOKINETICS

Doxycycline is well absorbed following oral administration, with absorption occurring primarily in the intestine. It is widely distributed to the heart, kidneys, lungs, muscle, pleural fluid, bronchial secretions, bile, saliva, synovial fluid, ascitic fluid, and aqueous and vitreous humor. Its steady-state volume of distribution is approximately 1.5 L/kg (2.2 lb), and its plasma protein binding ranges from 75% to 86% in dogs. Its elimination occurs mainly via feces (50%) in the form of an inactive metabolite through intestinal secretion. Only about 18% is excreted via bile salts, and renal excretion of up to 25% of the initial dose has been reported. The remainder of the drug is inactivated in the intestinal wall through chelation with Ca++ and Zn++ ions, which prevents enterohepatic recirculation (Sumano *et al.*, 2015).

12. WARNINGS

It should not be used in patients with hypersensitivity to this active ingredient. Its use is contraindicated in animals showing signs of esophagitis or dysphagia. It is not recommended for use in pregnant females (BSAVA, 2017; Plumb, 2008).

Incorrect use of this product may cause bacterial resistance. "It should not be administered in young animals because it can affect bone and tooth formation."

13. ADVERSE REACTIONS

In dogs and cats the most common side effects are nausea and vomiting. To minimize these effects, the medication may be administered with food (without a significant change in bioavailability). In cats, oral administration of doxycycline (without food or water) has been associated with the development of esophageal stricture; therefore, it is recommended that the tablet be given with at least 6 mL of water. Doxycycline therapy (especially long-term) may lead to fungal or bacterial "superinfections" due to the resulting dysbiosis (Plumb, 2008).

14. OVERDOSAGE

Oral overdose is associated with gastrointestinal disorders such as vomiting and/or diarrhea (Plumb, 2008).

15. DRUG INTERACTIONS

Do not administer concurrently with antacids.

Bismuth subsalicylate, kaolin and pectin reduce the absorption of doxycycline.

Oral administration of iron decreases the absorption of doxycycline; therefore, it is recommended to administer it 3 hours before or 2 hours after doxycycline administration.

An antagonistic effect between β -lactam and aminoglycoside antibiotics and doxycycline has been reported.

Phenobarbital may decrease the half-life of doxycycline.

Doxycycline decreases prothrombin activity in patients taking anticoagulants, e.g. warfarin. (Plumb, 2008).

16. INTERACTIONS WITH LABORATORY TESTS

Doxycycline may cause elevated urinary catecholamine levels when using fluorometric determination methods (Plumb, 2008).

Tetracyclines can cause false positive urine glucose results if the cupric sulfate determination method (Benedict's reagent, Clinitest®) and the glucose oxidase method (Clinistix®, Test-Tape®) are used (Plumb, 2008).

17. USE DURING PREGNANCY AND/OR LACTATION

In a system that evaluates drug safety during pregnancy in dogs and cats, doxycycline was classified as Class D: contraindicated for use in pregnant females, as it may cause congenital malformations or embryotoxicity. Tetracyclines are excreted in milk during lactation, so their use is not recommended during this stage (Plumb, 2008).

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-4196-148

22. SALE, DISPENSATION, AND/OR USE PROHIBITION

Prescription required.

Consult your veterinarian.

23. PRESENTATION

Box with bottle containing 30 or 100 tablets of 50 mg.

24. REFERENCES

- 24.1 BSAVA. Small Animal Formulary, Part A: canine and feline. 9th ed. UK. 2017.
- 24.2 Papich, M. Saunders Handbook of Veterinary Drugs: Small and Large Animal, 4th ed. Elsevier, USA, 2014.
- 24.3 Plumb, D. Veterinary Drug Handbook. Sixth Edition, Blackwell Publishing, Iowa, 2008.
- 24.4 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.



Diana A. de Regules Silva
Certified expert translator
+52 55.5431.4434
dianaderegules@me.com