



HOLLAND
DE MÉXICO

**TECHNICAL
DATA
SHEET**

Antiparasitics

1. VETERINARY MEDICATION NAME

Flagyplex®

2. PHARMACEUTICAL PRESENTATION

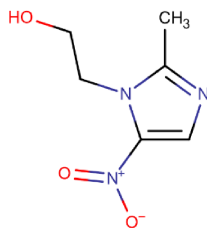
Oral suspension.

3. FORMULA

Each 100 ml contain:

Metronidazole benzoyl	5 g
Vehicle q.s.	100 ml

4. STRUCTURAL FORMULA



5. THERAPEUTIC INDICATIONS

Broad-spectrum antiparasitic and antibacterial indicated for the control and treatment of infections caused by *Trichomonas*, amoebae, and *Giardia* in dogs and cats, as well as enteric and systemic infections caused by anaerobic bacteria susceptible to metronidazole.

6. SPECTRUM

Protozoa: *Giardia* sp., *Trichomonas* sp., *Entamoeba histolytica*, *Balantidium coli*.

Anaerobic bacteria: *Bacteroides* spp., *Fusobacterium* spp., *Clostridium* spp., *Peptococcus* spp., *Peptostreptococcus* spp. (Papich, 2016; Plumb, 2008).

7. SPECIES

Canines and felines (Plumb, 2008).

8. ADMINISTRATION ROUTE

Oral (Plumb, 2008).

9. DOSAGE

General dosage:

Metronidazole: 25 mg/kg (2.2 lb) of body weight every 12 hours (BSAVA, 2017).

Flagyplex®

Canine: 1 mL per 2 kg (4.4 lb) of body weight every 12 h for a period of 5 to 7 days.

Felines: 0.5 mL per kg (2.2) of body weight every 12 hours for a period of 5 to 7 days.

The dosage may be modified at the discretion of the Veterinarian according to the type of infection.

10. MECHANISM OF ACTION

It has bactericidal activity for anaerobic bacteria, probably in a concentration-dependent manner. After entering the cell, it is reduced and produces unstable intermediates, some of which have antimicrobial activity. These cause extensive DNA strand breakage and inhibit the DNA repair enzyme, DNase-1. This reduction reaction occurs under anaerobic conditions and is insufficient to produce active metabolites in aerobic bacteria; therefore, metronidazole is only active against anaerobic bacteria. It is also active against many protozoa, but the mechanisms involved are not known. It is also known to possess a suppressive effect on the cellular immune response, which is important in inflammatory bowel disease (Maddison, 2008; Merton, 2012; Hsu, 2008).

11. PHARMACOKINETICS

Metronidazole is relatively well absorbed following oral administration. In dogs, oral bioavailability is high but varies between individuals, with reported ranges from 50% to 100%. If administered with food, absorption is enhanced, with peak levels occurring approximately one hour after administration. Metronidazole is highly lipophilic and distributes rapidly and extensively into most body tissues and fluids, including bone, abscesses, the central nervous system (CNS), and seminal fluid. Metronidazole is metabolized mainly in the liver through several biotransformation pathways and is eliminated through urine and feces. The elimination half-life of metronidazole in dogs with normal renal and hepatic function is 4 to 5 hours (Papich, 2016; Plumb, 2008).

12. WARNINGS

Do not administer in pregnant and lactating females (BSAVA, 2017; Plumb, 2008).

Do not administer if hypersensitive to nitromidazoles or in animals treated with phenobarbital, phenytoin or cimetidine (Plumb, 2008; USP, 2003).

"Use is prohibited in animals intended for human consumption or in any animal species other than those approved."

13. ADVERSE REACTIONS

Adverse effects reported in dogs include neurological disorders, lethargy, weakness, neutropenia, hepatotoxicity, hematuria, anorexia, nausea, vomiting and diarrhea (Maddison, 2008; Plumb, 2008).

14. OVERDOSAGE

Neurotoxic effects have been reported in dogs with doses of 67-129 mg/kg/day administered for 6 to 12 days. Clinical signs include severe ataxia, positional nystagmus, seizures, and head tilt (Maddison, 2008).

15. DRUG INTERACTIONS

It has been reported that metronidazole can decrease the metabolism of cimetidine (Plumb, 2008).

Phenobarbital or phenytoin may increase the metabolism of metronidazole (BSAVA, 2017; USP, 2003).

Metronidazole may prolong prothrombin time in patients receiving warfarin or other coumarin anticoagulants (Plumb, 2008).

16. INTERACTIONS WITH LABORATORY TESTS

Metronidazole may cause falsely decreased readings of aspartate transaminase (AST) and alanine transaminase (ALT) when using ultraviolet absorbance-based measurement methods (Plumb, 2008).

17. USE DURING PREGNANCY AND/OR LACTATION

Metronidazole may be teratogenic, therefore, it should not be used during pregnancy, especially in the first 3 weeks, unless the benefits to the mother outweigh the potential risks to the fetus. One of the routes of elimination of metronidazole is through milk, so its use in lactating females is not recommended due to its carcinogenic potential (Maddison, 2008; Plumb, 2008; USP, 2003).

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-4196-212

22. SALE, DISPENSATION, AND/OR USE PROHIBITION

Prescription required.

Consult your veterinarian.

23. PRESENTATION

Box containing a 60 mL bottle (2.03 fl oz).

24. REFERENCES

- 24.1 BSAVA. Small Animal Formulary. 9th. Zenith Media, 2017.
- 24.2 Hsu W. Handbook of Veterinary Pharmacology. 1st ed, Wiley-Blackwell, 2008.
- 24.3 Maddison, J. Small Animal Clinical Pharmacology. Elsevier, China, 2008.
- 24.4 Merton, D. Small Animal Clinical Pharmacology and Therapeutics. 2nd ed, USA, Elsevier, 2012.
- 24.5 Papich M. Saunders Handbook of Veterinary Drugs: Small and Large Animal. Elsevier, USA, 2016.
- 24.6 Plumb, D. Veterinary Drug Handbook. Sixth Edition, Blackwell Publishing, Iowa, 2008.
- 24.7 USP. Veterinary Pharmaceutical Information Monographs- Antibiotics. Journal of Veterinary Pharmacology and Therapeutics. 2003; 26, 2:144-148.

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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