



1. VETERINARY MEDICATION NAME

Rx Felvital® Tri-Defense

2. PHARMACEUTICAL FORM

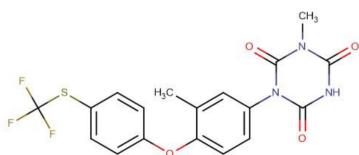
Oral suspension.

3. FORMULA

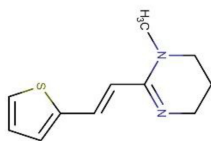
Each mL contains:

Toltrazuril	50 mg
Pyrantel pamoate	37.5 mg
Febantel	37.5 mg
Vehicle q.s.	1 mL

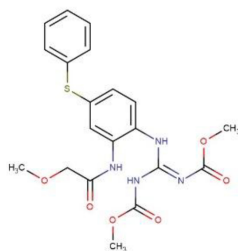
4. STRUCTURAL FORMULA



Toltrazuril



Pyrantel pamoate



Febantel

5. THERAPEUTIC INDICATIONS

Broad-spectrum internal antiparasitic indicated for the treatment of internal parasitoses caused by **Giardia, coccidia, Toxocara, ascarids, Ancylostoma, Uncinaria, and Trichuris** species susceptible to the active ingredients of the formulation, in felines and canines from three weeks of age. (Baert *et al.*, 1993; EMEA, 1998a; Marchiondo, 2016; Merton, 2012; Papich, 2016; Plumb, 2008).

6. SPECTRUM

Protozoa: *Giardia duodenalis*, *G. lamblia*, *Isospora felis*, *I. rivolta*, *I. canis*, *I. ohioensis*, *I. neorivolta*, *I. burrowsi*, *Toxoplasma gondii* and *Neospora caninum*.

Ascarids: *Toxocara canis*, *T. cati* and *Toxascaris leonina*.

Hookworms: *Uncinada stenocephala*, *Ancylostoma caninum*, *A. brasiliense* and *A. tubaeform*.

Trichuridae: *Trichuris vulpis*.

(Baert *et al.*, 1993; EMEA, 1998a; Papich, 2016; Marchiondo, 2016).

7. SPECIES

Felines and canines (Papich, 2016).

8. ADMINISTRATION ROUTE

Oral (Papich, 2016).

9. DOSAGE

General dosage:

Toltrazuril: 20 mg per kg of body weight (2.2 lb) (Plumb, 2008).

Pyrantel pamoate: 15 mg per kg of body weight (2.2 lb) (Plumb, 2008).

Febantel: 15 mg per kg of body weight (2.2 lb) (Maddison *et al.*, 2008).

Rx Felvital® Tri-Defense:

0.4 mL per kg of body weight (2.2 lb).

Coccidia and giardias: administer the dose for 3 consecutive days (Plumb, 2008).

Toxocara, ascarids, Ancylostoma, Uncinaria, and Trichuris: repeat the dose 15 days after the first treatment (Plumb, 2008).

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

10. MECHANISM OF ACTION

Toltrazuril

It is a triazinetrione derivative that leads to a reduction in respiratory chain enzymes in parasites, inhibits macrogamete wall formation of *Eimeria* spp. through endoplasmic reticulum swelling, Golgi apparatus disruption, abnormalities in the perinuclear space, and consequently interferes with cell division (EMA, 1998b; Maddison *et al.*, 2008).

Pyrantel pamoate

It causes a depolarizing neuromuscular blockade of the helminth's musculature. The paralyzed worms are expelled through intestinal peristalsis (EMA, 1998a; Long *et al.*, 2018; Mackenstedt *et al.*, 1993; Marchiondo, 2016).

Febantel

It inhibits energy metabolism by acting on enzyme systems and on the uptake of their energy sources. It prevents tubulin polymerization during microtubule growth causing inhibition of mitosis (Maddison *et al.*, 2008; Papich, 2016).

11. PHARMACOKINETICS

Toltrazuril

After oral administration, toltrazuril is absorbed in the intestine and distributed through the plasma to the different tissues (muscle, skin, fat, liver and kidneys). It is metabolized in the liver, where it undergoes oxidation by cytochrome P450 enzymes, and to a lesser extent, is metabolized via hydroxylation. Several metabolites are produced, the most important being toltrazuril sulfoxide and toltrazuril sulfone. The primary route of elimination for toltrazuril and its metabolites is fecal; only a small fraction is excreted via the renal route (EMA, 1998b; Hsu, 2008; Razan, 2020).

Pyrantel pamoate

It is administered orally and is minimally absorbed in the gastrointestinal tract. Peak plasma levels are reached within 2 to 3 hours. The absorbed drug is rapidly metabolized and excreted through urine and feces (Plumb, 2008).

Febantel

Febantel is a pro-benzimidazole compound that undergoes biotransformation in the liver into active anthelmintic metabolites such as fenbendazole and fenbendazole sulfoxide (oxfendazole) (Baert *et al.*, 1993).

12. WARNINGS

Do not administer to felines or canines under 3 weeks of age or to pregnant females (Plumb, 2008).

Do not co-administer with morantel, levamisole or cholinesterase inhibitors (Plumb, 2008).

Do not administer in debilitated animals (Plumb, 2008).

13. ADVERSE REACTIONS

In general, no serious adverse effects have been described; it is mentioned that mild gastrointestinal alterations may occur (Plumb, 2008).

14. OVERDOSAGE

Toltrazuril

Toltrazuril has a low acute toxicity, the clinical signs that may occur are reduced GI motility, diarrhea, polyuria and bristly coat (EMA, 2011).

Pyrantel pamoate

Pyrantel has a moderate safety margin, up to approximately 7 times the recommended dose, and generally does not produce toxic reactions (Plumb, 2008).

Febantel

Febantel has low acute toxicity; the oral LD₅₀ in laboratory rats and mice was greater than 10,000 mg/kg of body weight (EMA, 2004).

15. DRUG INTERACTIONS

It should not be administered together with levamisole or morantel, due to their similar mechanism of action. Organophosphates and diethylcarbamazine may increase the risk of adverse effects. Pyrantel and piperazine have an antagonistic mechanism of action; they should not be administered together. Concomitant use with other cholinergic compounds may cause toxicity (Plumb, 2008).

16. INTERACTIONS WITH LABORATORY TESTS

Toltrazuril, pyrantel pamoate, and febantel

No interactions with laboratory tests have been reported for these active ingredients.

17. USE DURING PREGNANCY AND/OR LACTATION

There are no reports on the safety in dogs and cats of the combination of toltrazuril, pyrantel pamoate and febantel during pregnancy and/or lactation, so its use is not recommended during these stages.

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-4196-290.

22. SALE, DISPENSATION, AND/OR USE PROHIBITION

Prescription required.

Consult your veterinarian.

Shake before use.

23. PRESENTATION

Box containing 30 mL bottle (1.01 fl oz).

24. REFERENCES

- 24.1 Baert *et al.* Pharmacokinetics and anthelmintic efficacy of febantel in the racing pigeon (*Columba livia*). *Journal of Veterinary Pharmacology and Therapeutics*, 1993; 16 (2), 223-231.
- 24.2 EMEA (1998a). Pyrantel embonate Summary Report. Committee for Veterinary Medicinal Products.
- 24.3 EMEA (1998b). Toltrazuril Summary Report. Committee for Veterinary Medicinal Products.
- 24.4 EMEA. EMA/CVMP/236066. Veterinary Medicines and Product Data Management, 2011.
- 24.5 EMEA. Febantel Summary Report. Committee for Veterinary Medicinal Products, 2004.
- 24.6 Hsu W. Handbook of Veterinary Pharmacology. 1st ed, Wiley-Blackwell, 2008.
- 24.7 Long *et al.* Principles and Practice of Pediatric Infectious Diseases. 5th ed., Elsevier, Canada, 2018.
- 24.8 Mackenstedt *et al.* Effects of pyrantel pamoate on adult and preadult *Toxocara canis* worms: an electron microscope and autoradiography study. *Parasitol Res*, 1993; 79, 567-578.
- 24.9 Maddison *et al.* Small Animal Clinical Pharmacology. 2nd ed., Saunders, Elsevier, China, 2008.
- 24.10 Marchiondo A. Pyrantel Parasiticide Therapy in Humans and Domestic Animals. Academic Press, Elsevier, USA, 2016.
- 24.11 Merton B. Small Animal Clinical Pharmacology. Elsevier, USA, 2012.
- 24.12 Papich M. Saunders Handbook of Veterinary Drugs: Small and Large Animal. Elsevier, USA, 2016.
- 24.13 Plumb *et al.* Veterinary Drugs Handbook. 6 ed. Blackwell, USA, 2008.
- 24.14 Razan *et al.* Pharmacokinetics of toltrazuril and its metabolites in pregnant and nonpregnant ewes and determination of their concentrations in milk, allantoic fluid, and newborn plasma. *J vet Pharmacol Therap.* 2020; 00:1-8.

- 24.15 Sykes J. Canine and feline Infectious Diseases. Elsevier, Saunders, China, 2014.

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 **3**-page document in Spanish, titled **"FICHA TÉCNICA"** into a **3**-page English document, titled **"TECHNICAL DATA SHEET"** both of which are attached herewith.



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