



NAME OF THE VETERINARY MEDICINAL PRODUCT

Rx Felvital® UT

2. PHARMACEUTICAL PRESENTATION

Oral suspension.

3. FORMULA

Each 3 ml contain:

N-acetyl-D-glucosamine (NAG) 250 mg

L-tryptophan 62.5 mg

Vehicle: hyaluronic acid, thickeners, flavoring and water q.s. 3 ml.

4. THERAPEUTIC INDICATIONS

Nutritional supplement adjuvant in the treatment of feline idiopathic cystitis. **Rx Felvital® UT** provides the essential components to support the regeneration and maintenance of the bladder's protective glycosaminoglycan (GAG) layer. It also contains L-tryptophan, a precursor of serotonin, a neurotransmitter that helps regulate susceptibility to stress, which, when chronic, can cause functional and structural changes in the bladder (Gao 2022; Gunn-Moore *et al.*, 2004; He *et al.*, 2022; Landsberg *et al.*, 2017; Panchaphanpong *et al.*, 2011, Porru *et al.*, 2012).

5. SPECIES

Feline (Gao 2022; Gunn-Moore *et al.*, 2004; He *et al.*, 2022; Landsberg *et al.*, 2017; Panchaphanpong *et al.*, 2011, Porru *et al.*, 2012).

6. APPLICATION METHOD

Oral (Gunn-Moore *et al.*, 2004; He *et al.*, 2022; Landsberg *et al.*, 2017; Spinosa *et al.*, 2017).

7. DOSAGE

3 mL of **Rx Felvital® UT** for every 5 kg (11 lbs) of body weight.(providing 250 mg NAG and 62.5 mg L-tryptophan) once daily (Forrester *et al.*, 2015; Panchaphanpong *et al.*, 2011).

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

8. MECHANISM OF ACTION

NAG

N-acetyl-D-glucosamine (NAG) is an exogenous form of glycosaminoglycan (GAG). GAGs coat the urothelium, preventing bacterial and crystal adhesion, while also protecting the urothelium from harmful or toxic substances in the urine. NAG helps maintain the amount of glycosaminoglycans in the urinary bladder wall, thereby

preventing the development of inflammation caused by idiopathic or interstitial cystitis. Additionally, NAG is known to have an effect on the number of polymorphonuclear cells and their chemotactic activity (Panchaphanpong *et al.*, 2011).

L-tryptophan

L-tryptophan is an essential amino acid, precursor of melatonin and serotonin. L-tryptophan has been implicated in the regulation of various behavioral processes and stress susceptibility. It has been used in the treatment of behavioral disorders in cats, including repetitive behaviors, vocalization, and aggression. Additionally, L-tryptophan has been reported to have anxiolytic effects (Landsberg *et al.*, 2017; Spinosa *et al.*, 2017).

9. PHARMACOKINETICS

NAG

It has been reported that orally administered NAG in cats is absorbed through the gastrointestinal tract and enters the circulatory system, resulting in an increased plasma concentration of glycosaminoglycans during the treatment period. Orally administered NAG is hydrolyzed to glucosamine in both animals and humans. NAG is a substrate for GAG biosynthesis, but its half-life is relatively short. The results of a study on glucosamine and NAG metabolism indicated that NAG was oxidized to a lesser extent in the body, resulting in higher urinary excretion (Panchaphanpong *et al.*, 2011; Takahashi *et al.*, 2009).

L-tryptophan

The intestinal absorption of orally ingested L-tryptophan at the apical membrane of enterocytes is mediated by the epithelial amino acid transport system B₀AT1, which is also responsible for the absorption of all other neutral amino acids and utilizes a Na⁺-dependent cotransport mechanism. The uptake of tryptophan by peripheral cells, such as tissue macrophages, has not yet been fully identified. Much more is known about the absorption of tryptophan across the blood-brain barrier, which plays a critical role in regulating serotonin synthesis in the brain. This process is based on a competitive transport mechanism shared by several neutral amino acids (LNAA). Consequently, increases in plasma LNAA concentrations reduce the rate of tryptophan uptake into the brain, thereby decreasing serotonin synthesis. Once in the gastrointestinal tract, tryptophan can enter several metabolic pathways: protein synthesis, the serotonin pathway, the kynurenine pathway, and bacterial degradation. Approximately 0.5% of ingested tryptophan is excreted unchanged in the urine (Keszthely *et al.*, 2009; Le Floc'h *et al.*, 2011; Riviere *et al.*, 2018; Spinosa *et al.*, 2017).

10. WARNINGS

Do not administer in animals with hypersensitivity to the components of the formula.

11. ADVERSE REACTIONS

NAG

Potential adverse effects are rare, but may include vomiting and diarrhea (He *et al.*, 2022).

L-tryptophan

No adverse effects have been described during its use (Spinosa *et al.*, 2017).

12. OVERDOSAGE

NAG

One study reported that a high dose (20 g) administered intravenously to human volunteers did not produce toxicity or alteration of blood glucose and insulin concentrations. Studies in rats showed no toxic effects related to the administration of NAG at doses of up to 5% in their diet over a 13-week period (Lee *et al.*, 2004).

L-tryptophan

Experimental data indicate that high tryptophan intake has no serious detrimental effects in humans or animals (le Floc'h *et al.*, 2011).

13. DRUG-DRUG INTERACTIONS

NAG

It could potentially increase the effects of warfarin, heparin or other drugs that affect coagulation, however, this assumption has not been confirmed (Plumb, 2008).

L-tryptophan

Serotonin syndrome is the term used for the potentially fatal toxicity that can occur when multiple medications enhancing serotonin activity are combined excessively. Very severe signs can be observed when a selective serotonin reuptake inhibitor is combined with tryptophan (Horwitz *et al.*, 2009; Norsworthy, 2011).

14. INTERACTIONS WITH LABORATORY TESTS

NAG

High doses of glycosaminoglycans could theoretically increase clotting time (prothrombin time) (Plumb, 2008).

L-tryptophan

Feeding cats a diet containing L-tryptophan was associated with a 43% increase in the plasma tryptophan/large neutral amino acids ratio and an approximate 40% reduction in urinary cortisol levels (Miyaji *et al.*, 2015).

15. USE DURING GESTATION AND/OR NURSING

NAG

There are no safety studies on this ingredient in pregnant or lactating animals (Plumb, 2008).

L-tryptophan

Dietary administration of 5-hydroxy-L-tryptophan to pregnant rats improved serotonin circulation, its synthesis by the mammary gland, as well as calcium absorption by the mammary gland and bone resorption, all without affecting milk production or the normal structure and function of the mammary gland. However, no information on its safety was found in pregnant cats (Laporta *et al.*, 2013).

16. 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.

17. EXPIRATION PERIOD

Expiration Period of the veterinary drug product as packaged for sale: 24 months.

18. HOLDER OF THE REGISTRY

HOLLAND DE MEXICO SA DE CV
Calle 21 Este, No 12, Col. Civac
Jiutepec, Morelos, CP 62578

19. REGISTRATION NUMBER

Q-4196-280.

20. PROHIBITION OF SALE, DISTRIBUTION AND/OR USE

Consult your veterinarian.
Shake before use.

21. PRESENTATION

Box containing 100 mL bottle (3.38 fl oz).

22. REFERENCES

- 22.1 Forrester *et al.* Feline Idiopathic Cystitis. *Vet Clin Small Anim.* 2015; 45 (4): 783-806.
- 22.2 Gao *et al.* The Effect of Chronic Psychological Stress on Lower Urinary Tract Function: An Animal Model Perspective. *Chronic Stress on Voiding Function*, 2022; 13:1-14.
- 22.3 Gunn-Moore *et al.* Oral glucosamine and the management of feline idiopathic cystitis. *Journal of Feline Medicine and Surgery*, 2004; 6: 219-225.
- 22.4 He *et al.* Prevalence, Risk Factors, Pathophysiology, Potential Biomarkers and Management of Feline Idiopathic Cystitis: An Update Review, 2022.

- 22.5 Horwitz *et al.* BSAVA Manual of Canine and Feline Behavioural Medicine. 2nd ed., BSAVA, India, 2012.
- 22.6 Keszthely *et al.* Understanding the role of tryptophan and serotonin metabolism in gastrointestinal function. *Neurogastroenterol Motil*, 2009; 21:1239-1249.
- 22.7 Landsberg *et al.* Therapeutic effects of an alphacazepine and L-tryptophan supplemented diet on fear and anxiety in the cat. *Journal of Feline Medicine and Surgery*, 2017; 19 (6): 594-602.
- 22.8 Laporta *et al.* Feeding 5-hydroxy-L-tryptophan during the transition from pregnancy to lactation increases calcium mobilization from bone in rats. *Domestic Animal Endocrinology* 2013; 44:176-184.
- 22.9 Le Floc'h *et al.* Tryptophan metabolism, from nutrition to potential therapeutic applications. *Amino Acids*, 2011; 41:1195-1205.
- 22.10 Lee *et al.* Subchronic toxicity study of dietary N-acetylglucosamine in F344 rats. *Food and Chemical Toxicology* 2004; 42:687-695.
- 22.11 Miyaji *et al.* Experimental Verification of the Effects on Normal Domestic Cats by Feeding Prescription Diet for Decreasing Stress. *Journal of Applied Animal Welfare Science* 2015; 18 (4): 355-362.
- 22.12 Norsworthy *et al.* *The Feline Patient*. 4th ed., Wiley Blackwell, Singapore, 2011.
- 22.13 Panchaphanpong *et al.* Effects of oral administration of N- acetyl-dglucosamine on plasma and urine concentrations of glycosaminoglycans in cats with idiopathic cystitis. *Am J Vet Res*, 2011; 72:843-850.
- 22.14 Plumb, D. *Veterinary Drug Handbook*. Sixth Edition, Blackwell Publishing, Iowa, 2008.
- 22.15 Porru *et al.* Impact of intravesical hyaluronic acid and chondroitin sulfate on bladder pain syndrome/interstitial cystitis. *Int Urogynecol J*, 2012; 23:1193-1199.
- 22.16 Riviere *et al.* *Veterinary Pharmacology and Therapeutics*. 10 th ed., Wiley Blackwell, India, India, 2018.
- 22.17 Spinosa *et al.* *Pharmacology Applied to Veterinary Medicine*, 6th ed. Gunabara Koogan, Rio de Janeiro: 2017.
- 22.18 Takahashi *et al.* Lack of chronic toxicity or carcinogenicity of dietary N-acetylglucosamine in F344 rats. *Food and Chemical Toxicology*, 2009; 47:462-471.

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 "**ft Felvital UT**," into a 3-page English document, titled "**ft Felvital UT**", both of which are attached herewith.



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