

Product Name: FELIMAZOLE 5 MG COATED TABLET
APVMA Approval No: 63928/120327



Label Name:	FELIMAZOLE 5 MG COATED TABLET
Signal Headings:	PRESCRIPTION ANIMAL REMEDY KEEP OUT OF REACH OF CHILDREN FOR ANIMAL TREATMENT ONLY READ SAFETY DIRECTIONS BEFORE OPENING OR USING
Constituent Statements:	5 mg/Tb THIAMAZOLE (Methimazole)
Claims:	Thiamazole is indicated for both the stabilization of feline hyperthyroidism prior to surgical thyroidectomy and for the long-term treatment of feline hyperthyroidism.
Net Contents:	100 Tablets
Directions for Use:	
Restrains:	
Contraindications:	Contraindicated for use in pregnant or lactating queens. Contraindicated for use in cats suffering from systemic disease, such as primary liver disease or diabetes mellitus. Contraindicated for use in cats showing signs of autoimmune disease. Contraindicated for use in animals with disorders of white blood cells, such as neutropaenia and lymphopaenia. Contraindicated for use in animals with platelet disorders and coagulopathies (particularly thrombocytopenia). Contraindicated for use in cats with hypersensitivity to thiamazole or the excipient, polyethylene glycol.

Precautions:	<p>Concurrent treatment with phenobarbital may reduce the clinical efficacy of thiamazole.</p> <p>Concurrent treatment with benzimidazole wormers is known to reduce the hepatic oxidation of these actives and may lead to increases in circulating levels.</p> <p>Thiamazole is immunomodulatory therefore this should be taken into account when considering vaccination programmes.</p>
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Side Effects:	<p>Side effects vary depending on dose regime and duration of treatment. In a clinical field study, approximately 20% of the cats experienced some form of adverse reaction, most frequently when the product was used for long-term treatment of hyperthyroidism. In many cases, clinical signs were mild and transitory, and not a reason for withdrawal of treatment. The more serious effects were usually reversible when medication was stopped. At doses of up to 15 mg, clinical side effects included: vomiting, loss of appetite, anorexia, lethargy, depressed or withdrawn demeanour, weakness, abnormal vocalisation, agitation, loose faeces/diarrhoea, skin lesions secondary to severe pruritus of the head and neck, bleeding diathesis and icterus associated with hepatopathy, and haematological abnormalities (eosinophilia, lymphocytosis, neutropaenia, lymphopaenia, slight leucopaenia, agranulocytosis, thrombocytopenia or haemolytic anaemia). These side effects resolved within 7-45 days after cessation of thiamazole therapy.</p> <p>Haematology must be monitored due to risk of leucopaenia or haemolytic anaemia. Any animal that suddenly appears unwell during therapy, particularly if they are febrile, should have a blood sample taken for routine haematology and biochemistry. Neutropaenic animals (neutrophil counts $<2.5 \times 10^9/L$) should be treated with prophylactic bactericidal antibacterial drugs and supportive therapy.</p> <p>Immunological side effects (anaemia, thrombocytopenia, serum anti-nuclear antibodies) can occur. Treatment should be stopped immediately and alternative therapy considered following a suitable period for recovery.</p> <p>Use of the product in cats with renal dysfunction should be subject to careful risk:benefit assessment by the clinician as reversal of hyperthyroidism may be associated with decreased glomerular filtration rate and a decline in renal function, unmasking the presence of underlying renal disease. Renal function should be monitored closely. During a long-term clinical study, 18 of 101 cats died or were euthanized; four of these deaths may have been related to treatment with thiamazole unmasking/accelerating chronic renal failure. As thiamazole can cause haemoconcentration, cats should always have access to drinking water.</p> <p>If overdosage occurs, stop treatment and give symptomatic and supportive care.</p>
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Dosage and Administration:	<p>For oral administration only.</p> <p>A starting regime of 2.5 mg twice a day is recommended for all cats. Studies have shown that incidence of and severity of adverse effects are reduced if this regime is followed.</p> <p>For the stabilisation of feline hyperthyroidism prior to surgical removal of the thyroid gland: One 2.5 mg tablet morning and evening. This should ensure euthyroidism within 3 weeks in most cases.</p> <p>For long-term treatment of hyperthyroidism: The starting dose should be 2.5 mg morning and evening. After 3 weeks, the dose should be titrated to effect according to the serum total T_4. Dose adjustments should be made by increments of 2.5 mg. The 5 mg tablet is suitable for cats requiring a higher dose. Wherever possible, the total daily dose should be divided into two and administered morning and evening. Tablets should not be split. The aim should be to achieve the lowest possible dose rate. Life-long treatment is required.</p>
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	<p>If more than 10 mg per day is required, animals should be monitored particularly carefully. The dose administered must not exceed 20 mg/day.</p> <p>For veterinarians contemplating a once daily dosing regime: it should be noted that efficacy studies were conducted using only a twice daily dosing regime; consequently, the efficacy of a once daily dose has not been established. Therefore, if a once daily dose of 5 mg is required to facilitate compliance, reduced efficacy may occur.</p> <p>Haematology, biochemistry and serum total T₄ should be assessed before initiating treatment and after 3 weeks, 6 weeks, 10 weeks, 20 weeks, and thereafter every 3 months and the dose titrated as necessary.</p>
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General Directions:	<p>The purpose of the drug is to control excessive production of thyroid hormones: thyroxine (T₄) and triiodothyronine (T₃), in order to achieve euthyroidism.</p> <p>The tablets are well absorbed following oral administration. Maximal plasma concentrations are achieved within 1-1½ hours after dosing and thiamazole is rapidly eliminated from blood (T_½ is approximately 4.5 - 5 hours). Administration of the tablets in a fasted state enhances absorption.</p>
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Withholding Periods:	
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Trade Advice:	
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Safety Directions:	Wash hands after use.
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First Aid Instructions:	If poisoning occurs, contact a doctor or Poisons Information Centre, Phone Australia 131 126.
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First Aid Warnings:	
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Additional User Safety:	<p>Do not break or crush tablets.</p> <p>Thiamazole may cause birth defects. Women of child bearing age are advised not to administer this product.</p> <p>Children and pregnant women should not come into contact with this drug. Keep children and pregnant women away from vomitus, faeces and urine of treated cats.</p> <p>Wear protective gloves to prevent direct contact with vomitus, faeces and urine of treated cats and/or when cleaning up broken or moistened tablets.</p> <p>Do not handle this product if you are allergic to hyperthyroidism inhibitors.</p> <p>Additional information is listed in the Safety Data Sheet.</p>
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Environmental Statements:	
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Disposal:	Dispose of container by wrapping with paper and putting in garbage. Unused product should be returned to the veterinary surgeon.
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Storage:

Store below 25°C (Air Conditioning) in a dry place. Keep the blister strips in the carton.