

# Felimazole 5 mg Coated Tablets

## Introduction



Company name: [Dechra Veterinary Products](#)  
Address: **(A business unit of Dechra Pharmaceuticals PLC)**  
**Cartmel Drive**  
**Harlescott**  
**Shrewsbury SY1 3TB**  
Telephone: **01743 441632**  
Fax: **01743 462111**  
Email: [info@dechra-uk.com](mailto:info@dechra-uk.com)  
Website: [www.dechra-uk.com](http://www.dechra-uk.com)

## Presentation

Orange sugar-coated biconvex tablets, each containing 5 mg Thiamazole (Methimazole).

Excipients:

Titanium Dioxide (E171)

Dispersed Sunset Yellow Lake 15005 (E110)

## Uses

Thiamazole is indicated for both the stabilisation of feline hyperthyroidism prior to surgical thyroidectomy and for the long-term treatment of feline hyperthyroidism. The purpose of the drug is to control excessive production of thyroid hormones: Thyroxine (T4) and Triiodothyronine (T3), in order to achieve euthyroidism.

## Dosage and administration

For oral administration only.

**The 5 mg tablet is suitable for cats requiring higher dose rates, or to facilitate compliance** (see below).

In the light of recent studies, and following the introduction of a 2.5 mg tablet, it is recommended to use the 2.5 mg tablet for stabilisation in the first instance.

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.

For long-term treatment of hyperthyroidism, the starting dose should be 2.5 mg twice daily. After 3 weeks, the dose should be titrated to effect according to the serum total T4. Dose adjustments should be made by increments of 2.5 mg. 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.

If, for reasons of compliance, once daily dosing with a 5 mg tablet is preferable, then this is acceptable although reduced efficacy can be expected compared to a twice daily regime. The 5 mg tablet is also suitable for cats requiring higher dose rates.

If more than 10 mg per day is required animals should be monitored particularly carefully. The dose administered must not exceed 20 mg/day.

For long-term treatment of hyperthyroidism the animal should be treated for life.

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.

## Contra-indications, warnings, etc

Do not use in pregnant or lactating females.

Do not use in cats suffering from systemic disease, such as primary liver disease or diabetes mellitus.

Do not use in cats showing signs of autoimmune disease.

Do not use in animals with disorders of white blood cells, such as neutropenia and lymphopenia.

Do not use in animals with platelet disorders and coagulopathies (particularly thrombocytopenia).

Do not use in cats with hypersensitivity to Thiamazole or the excipient, Polyethylene Glycol.

Concurrent treatment with Phenobarbital may reduce the clinical efficacy of Thiamazole.

Concurrent treatment with Benzimidazole wormers is known to reduce the hepatic oxidation of these actives and may lead to increases in circulating levels.

Thiamazole is immunomodulatory, therefore this should be taken into account when considering vaccination programmes.

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 control of hyperthyroidism. In many cases symptoms may be mild and transitory and not a reason for withdrawal of treatment. The more serious effects are mainly reversible when medication is stopped. At doses of up to 10-15 mg the clinical side effects were vomiting, inappetance/anorexia, lethargy, severe pruritus and excoriations of the head and neck, bleeding diathesis and icterus associated with hepatopathy, and haematological abnormalities (eosinophilia, lymphocytosis, neutropenia, lymphopenia, slight leucopenia, agranulocytosis, thrombocytopenia or haemolytic anaemia). These side effects resolved within 7-45 days after cessation of Thiamazole therapy.

Haematology must be monitored due to risk of leucopenia 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. Neutropenic animals (neutrophil counts  $<2.5 \times 10^9/l$ ) should be treated with prophylactic bactericidal antibacterial drugs and supportive therapy.

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.

Use of the product in cats with renal dysfunction should be subject to careful risk : benefit assessment by the clinician.

Due to the effect Thiamazole can have on the glomerular filtration rate, the effect of therapy on renal function should be monitored closely as deterioration of an underlying condition may occur.

As Thiamazole can cause an increase in haemoconcentration, cats should always have access to drinking water.

If overdosage occurs, stop treatment and give symptomatic and supportive care.

Following long-term treatment with Thiamazole in rodents, an increased risk of neoplasia in the thyroid gland has been shown to occur, but no evidence is available in cats.

*Operator warnings:* Wash hands after use.

Wash your hands with soap and water after handling litter used by treated animals.

Do not eat, drink or smoke while handling the tablet or used litter.

Do not handle this product if you are allergic to hyperthyroidism inhibitors.

Do not break or crush tablets.

As Thiamazole is a suspected human teratogen, women of child-bearing age should wear gloves when handling litter of treated cats.

In the event of accidental ingestion, seek medical advice immediately and show the package insert or the label to the physician.

*General precautions:* For animal treatment only.

## Pharmaceutical precautions

Do not store above 25°C. Keep the container tightly closed in order to protect from moisture. Keep out of the reach of children.

*Disposal:* Dispose of used packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

## Legal category

POM-V (previously POM)

## Packaging Quantities

White low density polyethylene tub with white low density polyethylene tamper evident lid containing 100 tablets.

## Further information

*Manufacturer:* Dales Pharmaceuticals, Snaygill Industrial Estate, Keighley Road, Skipton, North Yorkshire, BD23 2RW, UK.

## Marketing authorisation number

V<sub>M</sub> 01732/4111.