1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thiafeline 5 mg Film-coated Tablets for Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each tablet contains:

Active substance:
Thiamazole 5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Tablet core:	
Lactose monohydrate	
Povidone	
Sodium starch glycolate Type A	
Silica, colloidal anhydrous	
Magnesium stearate	
Coating:	
Hypromellose	
Cellulose, microcrystalline	
Lactose monohydrate	
Macrogol	
Titanium dioxide (E171)	0.15 mg
Sunset Yellow FCF (E110)	0.09 mg
Quinoline Yellow WS (E104)	0.075 mg

Orange film-coated biconvex tablets, 5.5 mm diameter.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

For the stabilisation of hyperthyroidism in cats prior to surgical thyroidectomy.
For the long-term treatment of feline hyperthyroidism.

3.3 Contraindications

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 pregnant or lactating females. Refer to section 3.7.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:
As thiamazole can cause haemoconcentration, cats should always have access to drinking water.
If more than 10 mg per day is required animals should be monitored particularly carefully.
Use of the veterinary medicinal product in cats with renal dysfunction should be subject to careful benefit-risk assessment by the clinician. Due to the effect thiamazole can have on reducing the glomerular filtration rate, the effect of therapy on renal function should be monitored closely as deterioration of an underlying condition may occur.
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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to thiamazole should avoid contact with the veterinary medicinal product.
Do not handle this veterinary medicinal product if you are allergic to anti-thyroid products. Do not break or crush tablets. If allergic symptoms develop, such as a skin rash, swelling of the face, lips or eyes or difficulty in breathing, you should seek medical attention immediately and show the package leaflet or the label to the physician.
Thiamazole may cause vomiting, epigastric distress, headache, fever, arthralgia, pruritus and pancytopenia. Treatment is symptomatic.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Do not eat, drink or smoke while handling the tablet or used litter.
Wash hands after use.
Wash hands with soap and water after handling litter used by treated animals.
As thiamazole is a suspected human teratogen, women of child-bearing age and pregnant should wear gloves when handling litter of treated cats.
Pregnant women should wear gloves when handling this veterinary medicinal product.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cats:

Uncommon (1 to 10 animals / 1,000 animals treated):	Vomiting[a]; Anorexia[a], Inappetence[a], Lethargy[a]; Pruritus[a,b], Excoriation[a,b];

	Prolonged bleeding[a,c,d]; Hepatopathy[a], Icterus[a,d]; Eosinophilia[a], Lymphocytosis[a], Neutropenia[a], Lymphopenia[a], Leucopenia[a,e], Agranulocytosis[a], Thrombocytopenia[a,g,h], Haemolytic anaemia[a].
Rare (1 to 10 animals / 10,000 animals treated):	Serum anti-nuclear antibodies[f,h], Anaemia[f,h].
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Lymphadenopathy[f,h].

[a] Resolves within 7-45 days after cessation of thiamazole therapy.
[b] Severe. Of the head and neck.
[c] Sign of bleeding diathesis.
[d] Associated with hepatopathy.
[e] Slight.
[f] Immunological side effect.
[g] Occurs uncommonly as a haematological abnormality and rarely as an immunological side effect.
[h] Treatment should be stopped immediately and alternative therapy considered following a suitable period for recovery.

Adverse events have been reported following long term control of hyperthyroidism. In many cases signs may be mild and transitory and not a reason for withdrawal of treatment. The more serious effects are mainly reversible when medication is stopped. 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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
Laboratory studies in rats and mice have shown evidence of teratogenic and embryotoxic effects of thiamazole. The safety of the veterinary medicinal product was not assessed in pregnant or lactating cats. Do not use in pregnant or lactating females.

3.8 Interaction with other medicinal products and other forms of interaction

Concurrent treatment with phenobarbital may reduce the clinical efficacy of thiamazole.
Thiamazole is known to reduce the hepatic oxidation of benzimidazole wormers and may lead to increases in their plasma concentrations when given concurrently.
Thiamazole is immunomodulatory, therefore this should be taken into account when considering vaccination programmes.

3.9 Administration routes and dosage

Oral use.

For the stabilisation of feline hyperthyroidism prior to surgical thyroidectomy and for the long term treatment of feline hyperthyroidism, the recommended starting dose is 5 mg per day.

Wherever possible, the total daily dose should be divided into two and administered morning and evening. Tablets should not be split.
If, for reasons of compliance, once daily dosing with a 5 mg tablet is preferable, then this is acceptable although the 2.5 mg tablet given twice daily may be more efficacious in the short term. The 5 mg tablet is also suitable for cats requiring higher dose rates.
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. At each of the recommended monitoring intervals, the dose should be titrated to effect according to the total T4 and to clinical response to treatment. Dose adjustments should be made in increments of 2.5 mg and the aim should be to achieve the lowest possible dose rate.
If more than 10 mg per day is required animals should be monitored particularly carefully.
The dose administered should not exceed 20 mg/day.
For long term treatment of hyperthyroidism the animal should be treated for life.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

In tolerance studies in young healthy cats, the following dose-related clinical signs occurred at doses of up to 30 mg/animal/day: anorexia, vomiting, lethargy, pruritus and haematological and biochemical abnormalities such as neutropenia, lymphopenia, reduced serum potassium and phosphorus levels, increased magnesium and creatinine levels and the occurrence of anti-nuclear antibodies. At a dose of 30 mg/day some cats showed signs of haemolytic anaemia and severe clinical deterioration. Some of these signs may also occur in hyperthyroid cats treated at doses of up to 20 mg per day.
Excessive doses in hyperthyroid cats may result in signs of hypothyroidism. This is however unlikely, as hypothyroidism is usually corrected by negative feedback mechanisms. Please refer to section 3.6: Adverse events.
If overdosage occurs, stop treatment and give symptomatic and supportive care.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QH03BB02.

4.2 Pharmacodynamics

Thiamazole acts by blocking the biosynthesis of thyroid hormone *in vivo*. The primary action is to inhibit binding of iodide to the enzyme thyroid peroxidase, thereby preventing the catalysed iodination of thyroglobulin and T_3 and T_4 synthesis.

4.3 Pharmacokinetics

Absorption
Following oral dosing in healthy cats, thiamazole is rapidly and completely absorbed with a bioavailability of >75 %. However, there is a considerable variation between animals.
Peak plasma levels occur approximately 0.5-1 hour after dosing (T_{max} = 0.69 hours). C_{max} is between 1.1 and 2.7 µg/ml (1.78 µg/ml) and half-life is 3.3 hours.

Distribution
From man and rats it is known that the drug can cross the placenta and concentrates in the foetal thyroid gland. There is also a high rate of transfer into breast milk.
The drug residence time in the thyroid gland is assumed to be longer than in the plasma.

Metabolism and elimination
The metabolism of thiamazole in cats has not been investigated, however, in rats thiamazole is rapidly metabolised in the thyroid gland. About 64 % of the administered dose being eliminated in the urine and only 7.8% excreted in faeces. This is in contrast with man where the liver is important for the metabolic degradation of the compound.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

Keep the blister in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

30 tablets in a cardboard carton containing 1 aluminium/PVC strips, each strip with 30 tablets.
60 tablets in a cardboard carton containing 2 aluminium/PVC strips, each strip with 30 tablets.
120 tablets in a cardboard carton containing 4 aluminium/PVC strips, each strip with 30 tablets.
150 tablets in a cardboard carton containing 5 aluminium/PVC strips, each strip with 30 tablets.
300 tablets in a cardboard carton containing 10 aluminium/PVC strips, each strip with 30 tablets.

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V

7. MARKETING AUTHORISATION NUMBER(S)

VPA10475/006/002

8. DATE OF FIRST AUTHORISATION

13/09/2013

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

04/04/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).