PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON FOR TABLET CONTAINER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimazole 5 mg Coated Tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Thiamazole 5 mg

3. PACKAGE SIZE

100 tablets

4. TARGET SPECIES

Cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Keep the container tightly closed in order to protect from moisture.
Keep the container in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBER

Vm 50406/5051
Vm 50406/3045

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE {CARTON FOR BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimazole 5 mg Coated Tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains:
Thiamazole 5 mg

3. PACKAGE SIZE

100 tablets

4. TARGET SPECIES

Cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.
Keep the blister strips in the outer carton.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

14. MARKETING AUTHORISATION NUMBER

Vm 50406/5051
Vm 50406/3045

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {TABLET CONTAINER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimazole

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Thiamazole 5 mg/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {BLISTER}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimazole

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Thiamazole 5 mg/tablet

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Felimazole 5 mg Coated Tablets for Cats

2. Composition

Each tablet contains:

Active substance:

Thiamazole	5 mg

Excipients:

Titanium Dioxide (E171)	0.500 mg
Beta carotene (E160a)	0.112 mg
Sodium methyl parahydroxybenzoate (E219)	0.0015 mg

Orange sugar-coated biconvex tablets, 5,5 mm diameter.

3. Target species

Cats.

4. Indications for use

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

5. 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 cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in pregnant or lactating females (please refer to 'Special warnings: Pregnancy and lactation').

6. Special warnings

Special precautions for safe use in the target species:
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.
As thiamazole can cause haemoconcentration, cats should always have access to drinking water.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash hands after use.
In case of accidental ingestion, seek medical advice 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.
Wash 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 veterinary medicinal product if you are allergic to antithyroid products. 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.
Do not break or crush tablets.
As thiamazole is a suspected human teratogen, women of child-bearing age and pregnant women should wear gloves when handling litter of treated cats.
Pregnant women should wear gloves when handling the veterinary medicinal product.

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.

Interaction with other medicinal products and other forms of interaction:
If your cat is being treated with any other medications advise your veterinary surgeon prior to the use of this veterinary medicinal product.
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.

Overdose:
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 the section ‘Adverse events.’
If overdosage occurs, stop treatment and immediately contact your veterinary surgeon.
Give symptomatic and supportive care.

<Special restrictions for use and special conditions for use:>

7. Adverse events

Cats

Uncommon (1 to 10 animals / 1,000 animals treated):	Vomiting[a]; Anorexia[a], Inappetence[a], Lethargy[a]; Pruritus[a,b] (itching), Excoriation[a,b] (self-trauma); Prolonged bleeding[a,c,d]; Hepatopathy[a] (liver disease), Icterus[a,d] (jaundice); Eosinophilia[a] (raised number of eosinophils), Lymphocytosis[a] (higher than normal level of lymphocytes), Neutropenia[a] (low levels of neutrophils), Lymphopenia[a] (low levels of lymphocytes), Leucopenia[a,e] (low levels of white blood cells), Agranulocytosis[a] (severely low level of white blood cells), Thrombocytopenia[a,g] (low amounts of platelets), Haemolytic anaemia[a] (reduction of red blood cells).
Rare (1 to 10 animals / 10,000 animals treated):	Serum anti-nuclear antibodies[f,h], Anaemia[f,h] (low levels of red blood cells).
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Lymphadenopathy[f,h] (enlarged lymph nodes).

[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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian.

You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

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 2.5mg 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 must not exceed 20 mg/day.
For long-term treatment of hyperthyroidism the animal should be treated for life.

9. Advice on correct administration

Follow the dosing instructions and timing of follow-up visits advised by your veterinary surgeon.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the container/blister and the carton after EXP. The expiry date refers to the last day of that month.

Tablet container: Keep the container tightly closed in order to protect from moisture. Keep the container in the outer carton.
Blister: Keep the blister strips in the outer carton.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 50406/5051
Vm 50406/3045

Pack sizes:
Tablet container: Cardboard box with a container of 100 tablets.
Blister: Carboard box with 4 blister strips, each blister strip containing 25 tablets.
Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder:

Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for batch release:
Genera Inc.
Svetonedeljska cesta 2
Kalinovica
10436 Rakov Potok
Croatia

Dales Pharmaceuticals Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

Local representative and contact details to report suspected adverse reactions:
Dechra Veterinary Products Limited
Sansaw Business Park
Hadnall
Shrewsbury
Shropshire
SY4 4AS
United Kingdom
Tel.: +44 (0)1939 211200

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

POM-V

Gavin Hall
Approved: 21 April 2026