ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimazole 5 mg/ml Oral Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Thiamazole 5 mg/ml

3. PACKAGE SIZE

30 ml
100 ml

4. TARGET SPECIES

Cats

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

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 NUMBERS

Vm 50406/3031

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

BOTTLE - 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimazole 5 mg/ml Oral Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Thiamazole 5 mg/ml

3. TARGET SPECIES

Cats

4. ROUTES OF ADMINISTRATION

Oral use.

Read the package leaflet before use.

5. WITHDRAWAL PERIODS

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Regulatory B.V.

9. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

BOTTLE - 30 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimazole

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Thiamazole 5 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 6 months.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Felimazole 5 mg/ml Oral Solution for Cats

2. Composition

Each 1 ml dose contains

Active substance:
Thiamazole 5 mg

Excipients:

Methyl parahydroxybenzoate (E218)	2.00 mg
Propyl parahydroxybenzoate	0.20 mg

Clear, light yellow to yellowish-brown solution.

3. Target species

Cats

4. Indications for use

For the stabilisation of hyperthyroidism 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 the sections on Pregnancy and Lactation.

6. Special warnings

Special warnings:
In order to enhance stabilisation of the hyperthyroid patient the same feeding and dosing schedule should be used daily.

Special precautions for safe use in the target species:
- If more than 10 mg per day (2 ml of the veterinary medicinal product) is required, animals should be monitored particularly carefully.
- Use of the veterinary medicinal 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 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 $<2.5 \times 10^9$/litre) should be treated with prophylactic bactericidal antibacterial drugs and supportive therapy.
- As thiamazole can cause haemoconcentration, cats should always have access to drinking water.
- Please refer to Section 8: 'Dosage for each species, routes and method of administration' for monitoring instructions.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
- As thiamazole is a suspected human teratogen and it is excreted in the breast milk, women of child-bearing age and lactating women must wear non-permeable single use gloves when handling the veterinary medicinal product, vomit or used litter of treated animals. If you are pregnant, think you may be pregnant or are attempting to conceive, you should not administer the veterinary medicinal product or handle the litter/vomit of treated cats.
- This veterinary medicinal product can cause allergic reactions after dermal contact. Do not handle this veterinary medicinal product if you are allergic to thiamazole or one of the excipients. 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 insert or the label to the physician.
- This veterinary medicinal product may cause skin and eye irritation. Avoid skin and eye contact including hand-to-eye contact. In case of accidental skin and/or eye contact, rinse exposed skin and/or eyes immediately with clean running water. If irritation develops, seek medical advice immediately and show the package insert or the label to the physician.
- Thiamazole may cause vomiting, epigastric distress, headache, fever, arthralgia (joint pain), pruritus (itching) and pancytopaenia (decrease in blood cells and platelets). Avoid oral exposure including hand-to-mouth contact, especially by children.
- Do not leave filled syringes unattended.
- Replace the cap immediately after filling the syringe.

- Wash hands with soap and water after handling the vomit of or used litter of treated animals.
- Do not eat, drink or smoke while handling the veterinary medicinal product, vomit or used litter of treated animals.
- Following administration of the veterinary medicinal product, any residual veterinary medicinal product remaining on the tip of the dosing syringe should be wiped off with a tissue. The contaminated tissue should be immediately disposed of. The used syringe should be stored with the veterinary medicinal product in the original carton.
- In the case of accidental ingestion, seek medical advice immediately and show the package insert or the label to the physician.
- Wash hands after use.

Pregnancy and lactation
Laboratory studies in rats and mice have shown evidence of teratogenic and embryotoxic effects of thiamazole. The safety of the 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:
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 Section 7: Adverse events.
If overdosage occurs, stop treatment and give symptomatic and supportive care.

Major incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. Adverse events

Adverse reactions 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 and, in these cases, treatment should be stopped immediately and alternative therapy considered, following a suitable period for recovery.

Uncommon (1 to 10 animals / 1,000 animals treated):	Vomiting[1], Anorexia[1], Inappetence[1], Lethargy[1] Pruritus[1,2], Excoriation[1,2] Prolonged bleeding[1,3,4] Icterus[1,4], Hepatopathy[1] Eosinophilia[1], Lymphocytosis[1], Neutropenia[1], Lymphopenia[1], Leucopenia[1] (slight), Agranulocytosis[1] Thrombocytopenia[1,5,6], Haemolytic anaemia[1]
Rare (1 to 10 animals / 10,000 animals treated):	Autoimmune disorder (serum anti-nuclear antibodies)
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Lymphadenopathy[5], Anaemia[5]

[1] These side-effects resolve within 7-45 days after cessation of thiamazole therapy.
[2] Severe and of the head and neck.
[3] Sign of a bleeding diathesis.
[4] Associated with hepatopathy.
[5] Immunological side-effect.
[6] Occurs uncommonly as a haematological abnormality and rarely as an immunological side effect.

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. 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.

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 (1 ml of the veterinary medicinal product).
Wherever possible, the total daily dose should be divided into two equal doses and administered morning and evening.
If, for reasons of compliance, once daily dosing is preferable, then this is acceptable, although the twice-daily dose may be more efficacious in the short term.
Haematology, biochemistry and serum total T_4 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 T_4 and to clinical response to treatment. Dose adjustments should be made in increments of 2.5 mg (0.5 ml of the veterinary

medicinal product) and the aim should be to achieve the lowest possible dose rate. In cats that require particularly small dose adjustments, increments of 1.25 mg of thiamazole (0.25 ml of the veterinary medicinal product) can be used.
If more than 10 mg per day is required (2 ml of the veterinary medicinal product) animals should be monitored particularly carefully.
The dose administered should not exceed 20 mg/day (4 ml of the veterinary medicinal product).
For long-term treatment of hyperthyroidism, the animal should be treated for life.

9. Advice on correct administration

In order to administer the dose accurately, use the syringe provided in the package. The syringe fits on the bottle and is graduated in 0.25 mg increments up to 5 mg. Withdraw the required dose and administer the veterinary medicinal product directly into the cat's mouth.

10. Withdrawal periods

11. Special storage precautions

Keep out of the sight and reach of children.

This veterinary medicinal product does not require any special storage conditions.

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after Exp. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 6 months

12. Special precautions for disposal

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 material derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

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 50406/3031

Plastic bottles containing 30 ml and 100 ml. The veterinary medicinal product is supplied with a 1 ml plastic measuring syringe for administration of the solution to the animal. The syringe is graduated in 0.25 mg increments up to 5 mg. Each closed bottle and accompanying syringe is contained in a cardboard carton.

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 and contact details to report suspected adverse reactions:
Dechra Regulatory B.V.
Handelsweg 25
5531 AE Bladel
The Netherlands

Manufacturer responsible for batch release:
Genera Inc.
Svetonedeljska Cesta 2
Kalinovica
Rakov Potok
Sveta Nedelja
Zagrebacka Zupanija
10436
Croatia

17. Other information

Gavin Hall
Approved: 25 April 2025