ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON FOR TABLET CONTAINER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimazole 5 mg Coated Tablets for Cats
Thiamazole

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 tablet contains: Active substance: Thiamazole (Methimazole) 5 mg.
Excipients:
Titanium Dioxide (E171)
Beta Carotene (E160a)

3. PHARMACEUTICAL FORM

Coated Tablets

4. PACKAGE SIZE

100 Tablets

5. TARGET SPECIES

Cats

6. INDICATIONS

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

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.
For oral administration only.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.
For user warnings, please read the package leaflet.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBERS

UK: Vm 10434/4061 | POM-V |

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

OTHER INFORMATION
Veterinary medicinal product authorised for use in UK and IE.

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON FOR BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimazole 5 mg Coated Tablets for Cats
Thiamazole

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 tablet contains: Active substance: Thiamazole (Methimazole) 5 mg.
Excipients:
Titanium Dioxide (E171)
Beta Carotene (E160a)

3. PHARMACEUTICAL FORM

Coated Tablets

4. PACKAGE SIZE

100 Tablets

5. TARGET SPECIES

Cats

6. INDICATIONS

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

7. METHOD AND ROUTE OF ADMINISTRATION

Read the package leaflet before use.
For oral administration only.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.
For user warnings, please read the package leaflet.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBERS

UK: Vm 10434/4061 | POM-V

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

OTHER INFORMATION
Veterinary medicinal product authorised for use in UK.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimazole 5 mg Coated Tablets for Cats
Thiamazole

2. QUANTITY OF THE ACTIVE SUBSTANCE

1 tablet contains:
Active substance: Thiamazole (Methimazole) 5 mg.
Excipients:
Titanium Dioxide (E171); Beta Carotene (E160a).

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

100 Tablets

4. ROUTE OF ADMINISTRATION

For oral administration only.

5. WITHDRAWAL PERIOD

[Not applicable.]

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP: {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

OTHER INFORMATION

For user warnings, please read the package leaflet.
To be supplied only on veterinary prescription.

Veterinary medicinal product authorised for use in UK.
Keep out of the sight and reach of children.
Marketing authorisation holder: Dechra Limited, United, Kingdom

UK: Vm 10434/4061	POM-V

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimazole 5 mg
Coated tablets for cats
Thiamazole

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Dechra Limited

3. EXPIRY DATE

EXP:

4. BATCH NUMBER

Lot:

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Felimazole 5 mg Coated Tablets for Cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

Manufacturer for the 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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felimazole 5 mg Coated Tablets for Cats
Thiamazole (Methimazole)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Orange sugar-coated biconvex tablets.
1 tablet contains 5 mg Thiamazole (Methimazole).
Excipients: Titanium Dioxide (E171); Beta Carotene.

4. INDICATIONS

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 cats with hypersensitivity to thiamazole or the excipient, polyethylene glycol.
Do not use in pregnant or lactating females.
Please refer to 'Special warnings'.

6. ADVERSE REACTIONS

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.
Adverse reactions are uncommon. The most common clinical side effects that are reported include 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 resolve within 7-45 days after cessation of thiamazole therapy.
Possible immunological side effects include anaemia, with rare side effects including thrombocytopenia and serum anti-nuclear antibodies, and, very rarely, lymphadenopathy. Treatment should be stopped immediately and alternative therapy considered following a suitable period for recovery.
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.
If you notice any serious effects or any other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

8. DOSAGE FOR EACH SPECIES, ROUTE AND METHOD OF ADMINISTRATION

For oral administration only.
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 PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.
Do not use after the expiry date which is stated on the label and carton after EXP.
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 carton.

12. SPECIAL WARNINGS

As thiamazole can cause haemoconcentration, cats should always have access to drinking water.

Special precautions for use in animals
If more than 10 mg per day is required animals should be monitored particularly carefully.
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 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
Wash hands after use.
In the 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 pancytopaenia. 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 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 label to the doctor.
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 product.

Use during pregnancy or 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 the Section: Adverse reactions.
If overdosage occurs, stop treatment and give symptomatic and supportive care.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS

Any unused veterinary medicinal product or waste material derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

03/2019

15. OTHER INFORMATION

For animal treatment only.
To be supplied only on veterinary prescription.

Container of 100 tablets.
Blister pack of 100 tablets.
Not all pack sizes may be marketed.

Veterinary medicinal product authorised for use in UK and IE.

UK: Vm 10434/4061	POM-V	Prescription Only Medicine - Veterinarian

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder:
Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, United Kingdom.

Approved: 18 June 2019