ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

OUTER CARTON / CARDBOARD BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thiafeline 5 mg Film-coated Tablets for Cats
Thiamazole

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains
Thiamazole 5 mg

3. PHARMACEUTICAL FORM

Film-coated tablet.

4. PACKAGE SIZE

30 tablets
60 tablets
120 tablets
150 tablets
300 tablets

5. TARGET SPECIES

Cats.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

Women of child-bearing age and pregnant women should wear gloves when handling the product or litter of treated cats

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

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

Disposal: read package leaflet.

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 SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.
Wilgenweg 7
3421 TV Oudewater
The Netherlands

16. MARKETING AUTHORISATION NUMBER

41821/4006

17. MANUFACTURER'S BATCH NUMBER

LOT

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Aluminium/PVC strip with 30 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thiafeline 5 mg Film-coated Tablets for Cats
Thiamazole

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Le Vet Beheer B.V.

3. EXPIRY DATE

EXP: {month/year}

4. BATCH NUMBER

LOT

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For Animal Treatment Only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

THIAFELINE 5 mg Film-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:
Name: Le Vet Beheer B.V.
Address: Wilgenweg 7
3421 TV Oudewater
The Netherlands

Manufacturer responsible for batch release:
Name: Lindopharm GmbH
Address: Neustrasse 82
D-40721 Hilden
Germany

Name: Lelypharma B.V.
Address: Zuiveringweg 42
8243 PZ Lelystad
The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thiafeline 5 mg Film-coated Tablets for Cats
Thiamazole

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each tablet contains:

Active substance:

Thiamazole	5	mg

Excipient(s):

Titanium dioxide (E171)	0.15	mg
Sunset Yellow FCF (E110)	0.09	mg
Quinoline Yellow WS (E104)	0.075	mg

Oorange film-coated, biconvex tablet (5.5 mm diameter).

4. INDICATION(S)

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 pregnant or lactating females.
Do not use in cases of hypersensitivity to thiamazole or to any of the excipients.

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 reported include, 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.
Possible immunological side effects include anaemia, with rare side effects including thrombocytopenia and serum anti-nuclear antibodies, and, very rarely, lymphadenopathy can occur. 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.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

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

Administration route
Oral use.
Amounts to be administered

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.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the container in the outer package in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after “EXP”. The expiry date refers to the last date of that month.

12. SPECIAL WARNING(S)

Special precautions for use in animals
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 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
People with known hypersensitivity to thiamazole should avoid contact with the veterinary medicinal product.
Do not handle this 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 label to the doctor.
Thiamazole may cause vomiting, epigastric distress, headache, fever, arthralgia, pruritus and pancytopaenia. Treatment is symptomatic.
In the 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 product.

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.

Overdose (symptoms, emergency procedures, antidotes)(if necessary)
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 4.6: Adverse reactions.
If overdosage occurs, stop treatment and give symptomatic and supportive care.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT 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.
Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2019

15. OTHER INFORMATION

Package (size)
30 tablets in a cardboard carton containing 1 aluminium/pvcstrips 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.

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

Approved: 25 April 2019