ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thyrasol 5 mg/ml, Oral solution for cats
thiamazole

2. STATEMENT OF ACTIVE SUBSTANCES

Thiamazole 5.0 mg/ml

3. PHARMACEUTICAL FORM

Oral solution.
Colourless to slightly brownish, turbid, viscous solution.

4. PACKAGE SIZE

1x 30 ml
1x 50 ml
1x 100 ml

5. TARGET SPECIES

Cats.

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

This product may be harmful for the user and is harmful for the unborn child. Avoid exposure.
See package leaflet for full list of user safety warnings.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 90 days

11. SPECIAL STORAGE CONDITIONS

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

CP Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 20916/5004

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGE

Amber glass or Plastic (HDPE) bottle 100 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thyrasol 5 mg/ml, Oral solution for cats
thiamazole

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Thiamazole 5.0 mg/ml

3. PHARMACEUTICAL FORM

Oral solution.
Colourless to slightly brownish, turbid, viscous solution.

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

100 ml bottle

5. TARGET SPECIES

Cats.

6. INDICATION(S)

7. ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

This product may be harmful for the user and is harmful for the unborn child. Avoid exposure.
See package leaflet for full list of user safety warnings

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 90 days

11. SPECIAL STORAGE CONDITIONS

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY"

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

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

CP Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

16. MARKETING AUTHORISATION NUMBER

Vm 20916/5004

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Amber glass or Plastic (HDPE) bottle 30 and 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thyrasol 5 mg/ml, Oral solution for cats
thiamazole

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Thiamazole 5.0 mg/ml

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

30 ml bottle
50 ml bottle

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot: {number}

7. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 90 days

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Thyrasol 5 mg/ml, Oral solution 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 and manufacturer responsible for batch release:
CP Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thyrasol 5 mg/ml, Oral solution for cats
thiamazole

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Active substance:
Thiamazole 5.0 mg/ml

Excipients:
Sodium benzoate (E211) 1.5 mg/ml

Colourless to slightly brownish, turbid, viscous solution.

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 cases of hypersensitivity to the active substance or to any of the excipients.
Do not use during pregnancy or lactation.
Please refer to pregnancy or lactation in section 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, weight-loss, 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 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. Alternatively you can report via your national reporting system {national system details}

7. TARGET SPECIES

Cats.

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

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 (= 1 mL of the product) per day.
Wherever possible, the total daily dose should be divided into two and administered morning and evening.
The dose should be administered directly in the mouth using the syringe.

For oral use.

9. ADVICE ON CORRECT ADMINISTRATION

If, for reasons of compliance, once daily dosing is preferable, then this is acceptable although a 2.5 mg dose (= 0,5 mL of the product) given twice daily may be more efficacious in the short term.
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.
Standard 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.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.
The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

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

Special precautions for use in animals:
If more than 10 mg of thiamazole per day is required animals should be monitored particularly carefully.
As thiamazole can cause haemoconcentration, cats should always have access to drinking water.
Use of the 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 renal impairment may occur.
Haematology must be monitored due to risk of leucopenia or haemolytic anaemia.
Any animal that suddenly appears unwell during therapy, particularly if it is 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, if needed according to the benefit/risk assessment of the prescribing veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity (allergy) to thiamazole, or one of the excipients, should avoid contact with the veterinary medicinal product. 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.
This product may cause skin and/or eye irritation. Avoid skin and eye contact including hand to eye contact.
In case of accidental skin and/or eye contact, rinse skin and/or eyes immediately with clean running water. If irritation develops, seek medical advice.
Wash hands with soap and water after administration of the product and handling the vomit of or litter used by treated animals.
Thiamazole may cause gastrointestinal disturbances, headache, fever, joint pain, pruritus (itching) and pancytopaenia (decrease in blood cells and platelets).
Avoid oral exposure, including hand-to-mouth contact.
Do not eat, drink or smoke while handling the product or used litter.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Do not leave filled syringes unattended.
Following administration of the product any residual product remaining on the tip of the dosing syringe should be wiped clean with a tissue. The contaminated tissue should be immediately disposed of.
The used syringe should be stored with the product in the original carton.
As thiamazole is a suspected human teratogen, women of child-bearing age must wear non-permeable single-use gloves when administering the product or handling the litter/vomit of treated cats.
If you are pregnant, think you may be pregnant or are attempting to conceive, you should not administer the product or handle the litter/vomit of treated cats.

Pregnancy and lactation:
Do not 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 has not been assessed in pregnant or lactating cats.

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 (symptoms, emergency procedures, antidotes):
In tolerance studies in young healthy cats, the following dose-related clinical signs occurred at doses of up to 30 mg of thiamazole/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 of thiamazole/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 of thiamazole 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 point 6: Adverse reactions.
If overdosage occurs, stop treatment and give symptomatic and supportive care.

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

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 product should be disposed of in accordance with local requirements.

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.

15. OTHER INFORMATION

Amber type III glass or high density polyethylene (HDPE) screw bottles containing 30 mL, 50 mL and 100 mL product, with child resistant polypropylene (PP) screw cap and low density polyethylene (LDPE) syringe in-lay.
1.0 ml oral dosing syringe graduated in 0.01 mL increments with polypropylene (PP) body and high density polyethylene (HDPE) plunger or 1.5 mL oral dosing syringe graduated in 0.05 mL increments with low density polyethylene (LDPE) body and polystyrene (PS) plunger.

Pack sizes:
Carton box holding 1 vial of 30 mL and 1 graduated syringe Carton box holding 1 vial of 50 mL and 1 graduated syringe Carton box holding 1 vial of 100 mL and 1 graduated syringe

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.

Gavin Hall

Approved 07 June 2024