LABELLING AND PACKAGE LEAFLET

LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

30ml and 100ml Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thyronorm 5 mg/ml Oral Solution for Cats
Thiamazole

2. STATEMENT OF ACTIVE SUBSTANCES

Thiamazole 5 mg/ml

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

30 ml
100 ml

5. TARGET SPECIES

Cats

6. INDICATION(S)

To be included on product cartons where permissible and when font size considerations permit

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

9. SPECIAL WARNING(S), IF NECESSARY

Thiamazole may cause harm to the unborn child.
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.

Women of child bearing age must wear gloves.
Read package leaflet for full user warnings.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 6 months
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

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

Read the package leaflet before use.

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.

<***Supply Category to be completed nationally***>

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

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4399

17. MANUFACTURER'S BATCH NUMBER

BN

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml PET Vial Immediate Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thyronorm 5 mg/ml Oral Solution for Cats
Thiamazole

2. STATEMENT OF ACTIVE SUBSTANCES

Thiamazole 5 mg/ml

3. PHARMACEUTICAL FORM

Oral solution

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cats

6. INDICATION(S)

To be included on product labels where permissible and when font size considerations permit

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

9. SPECIAL WARNING(S), IF NECESSARY

Thiamazole may cause harm to the unborn child.
Read package leaflet for full user warnings.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 6 months
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

Read the package leaflet before use.

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

Read the package leaflet before use.

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.

<***Supply Category to be completed nationally***>

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

Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

16. MARKETING AUTHORISATION NUMBER(S)

Vm 02000/4399

17. MANUFACTURER'S BATCH NUMBER

BN

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

30ml PET Vial Immediate Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thyronorm 5 mg/ml Oral Solution for Cats
Thiamazole

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Thiamazole 5 mg/ml

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

30 ml

4. ROUTE(S) OF ADMINISTRATION

Oral use

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

BN

7. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the container: 6 months
Once broached use by…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only. To be supplied only on veterinary prescription.
<Supply category to be completed nationally>

PACKAGE LEAFLET FOR:

Thyronorm 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:
Norbrook Laboratories Limited
Station Works
Camlough Road
Newry
Co. Down
BT35 6JP
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Thyronorm 5 mg/ml Oral Solution for Cats
Thiamazole

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

Each ml contains:

Active substance:
Thiamazole 5 mg

Excipient:
Sodium Benzoate (E211) 1.5 mg

An off-white to light yellow opaque 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 liver disease or diabetes mellitus.
Do not use in cats showing signs of autoimmune disease such as anaemia, multiple inflamed joints, skin ulceration and crusting.
Do not use in animals with disorders of white blood cells, such as neutropenia and lymphopenia. Symptoms may include lethargy and increased susceptibility to infection. Do not use in animals with platelet disorders and coagulopathies (particularly thrombocytopenia). Symptoms may include bruising and excessive bleeding from wounds.

Do not use in pregnant or lactating females.
Do not use in known cases of hypersensitivity to the active substance 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.

Possible immunological side effects include anaemia, with rare side effects including thrombocytopenia and serum anti-nuclear antibodies, and, very rarely, lymphadenopathy can occur. Symptoms may include bruising, excessive bleeding, multiple inflamed joints and skin changes such as crusting and ulceration. Treatment should be stopped immediately and alternative therapy considered following a suitable period of 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.

Adverse reactions are uncommon. The most common clinical side effects that are reported include

- vomiting
- inappetance/anorexia
- lethargy (extreme tiredness)
- severe pruritus and excoriations of the head and neck
- jaundice (yellow discolouration) of membranes of the mouth, eye and skin associated with liver disease
- increased bleeding and /or bruising associated with liver disease
- haematological (blood cell) 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.

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

Oral use only.
The product should be administered directly into the mouth of the cat. Do not administer in food as efficacy of the product when administered via this route has not been established.

The recommended starting dose is 5 mg of thiamazole (1 ml of the product) per day.
The total daily dose should be divided into two and administered morning and evening. If, for reasons of compliance, once daily dosing is preferable, then this is acceptable, although a 2.5mg dose (=0.5ml of the product) given twice daily may be more efficacious in the short term. In order to enhance stabilisation of the hyperthyroid patient the same dosing schedule relative to feeding should be used daily.

After regular check-ups your veterinarian may adjust the dose.
For long-term treatment of hyperthyroidism, the animal should be treated for life.

Additional information for the treating veterinarian:
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 of thiamazole (0.5 ml of the 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 product) can be used. If total T4 concentration drops below the lower end of the reference interval, and particularly if the cat is showing clinical signs of iatrogenic hypothyroidism (e.g. lethargy, inappetence, weight gain and/or dermatological signs such as alopecia and dry skin), consideration should be given to reducing the daily dosage and/or dosing frequency.

If more than 10 mg of thiamazole per day is required animals should be monitored particularly carefully.

The dose administered should not exceed 20 mg of thiamazole per day.

9. ADVICE ON CORRECT ADMINISTRATION

Follow the dosing instructions and duration of treatment advised by the veterinary surgeon.

10. WITHDRAWAL PERIOD

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Keep the container tightly closed.
This veterinary medicinal product does not require any special temperature storage conditions.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton after 'EXP'.
Shelf life after first opening the container: 6 months.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.

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:
Cats should always have access to drinking water.
Please inform the veterinarian if your cat has kidney problems.
If your cat suddenly appears unwell during treatment, particularly if s/he is febrile (has a high temperature), s/he should be examined by a veterinarian as soon as possible and have a blood sample taken for routine haematology.

Information for the treating veterinarian:
If more than 10 mg of thiamazole 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 renal impairment may occur.
Haematology must be monitored due to risk of leucopenia or haemolytic anaemia before initiating treatment and closely afterwards.
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.
Please refer to the “Dosage for each species, route(s) and method of administration” section of this package leaflet for monitoring instructions.
As thiamazole can cause haemoconcentration, cats should always have access to drinking water.
In hyperthyroid cats gastrointestinal disorders are common and may interfere with the success of the oral therapy.

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 or eye irritation. Avoid eye contact including hand to eye contact. In case of accidental eye contact, rinse 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. Wash any spillages or spatter from skin immediately.
Thiamazole may cause gastrointestinal disturbances, headache, fever, joint pain, pruritus (itching) and pancytopaenia (decrease in blood cells and platelets).
Avoid dermal and 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.

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 in pregnant or lactating females.

Additional information for the treating veterinarian:
Laboratory studies in rats and mice have shown evidence of teratogenic and embryotoxic effects of thiamazole. In cats, the safety of the veterinary medicinal product has not been established during pregnancy or lactation. From man and rats it is known that the drug can cross the placenta and

concentrates in the foetal thyroid gland. There is also a high rate of transfer into breast milk.

Interaction with other medicinal products and other forms of interaction:
Please inform the veterinarian if your cat is receiving any other medicines or if your cat is going to be vaccinated.

Information for the treating veterinarian:
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):
If you think you have given your cat more than you should (an overdose), stop treatment and contact your veterinarian who may need to give symptomatic and supportive care.
For signs of overdose, please refer to the “Adverse reactions” section of this package leaflet.

Information for the treating veterinarian:
In tolerance studies in young healthy cats, the following dose-related clinical signs occurred at doses of up to 30 mg 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 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 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 the “Adverse reactions” section of this package leaflet.
If overdose 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.

14. 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

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

<Supply category to be completed nationally>

Package Information

The product is available in 30 ml and 100 ml presentations.

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: 20 July 2024