

Thyronorm® 5 mg/ml Oral Solution for Cats

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.

The total daily dose should be divided into two and administered morning and evening. In order to enhance stabilisation of the hyperthyroid patient the same dosing schedule relative to feeding should be used daily.

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 case of hypersensitivity to the active substance or to any of the excipients.

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

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 x 10⁹/l) should be treated with prophylactic bactericidal antibacterial drugs and supportive therapy.

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

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.

Thiamazole may cause gastrointestinal disturbances, headache, fever, joint pain, pruritus (itching) and pancytopenia (decrease in blood cells and platelets). In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Avoid dermal and oral exposure, including hand-to-mouth contact. Do not eat, drink or smoke while handling the product or used litter.

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 from skin immediately.

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.

This product may cause 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.

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.

Adverse reactions (frequency and seriousness)

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, inappetence/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 can occur. 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.

Legal Category: UK: POM-V IE: POM

Thyronorm 5 mg/ml Oral Solution for Cats contains 5mg/ml thiamazole.

For animal treatment only.

Keep out of the reach and sight of children.

Manufactured and distributed in NI by: Norbrook Laboratories Ltd, Station Works, Newry, Co. Down, BT35 6JP.

Distributed in GB by: Norbrook Laboratories (GB) Ltd, 1 Saxon Way East, Oakley Hay Industrial Estate, Corby, NN18 9EX.

Distributed in ROI by: Norbrook Laboratories (Ireland) Ltd, Rossmore Industrial Estate, Monaghan, County Monaghan.

Further information is available from Norbrook Laboratories.

Tel: UK 01536 741147
NI +44 (0)28 3026 4435
ROI +353 (0)47 81655
Email: enquiries@norbrook.co.uk

The full Summary of Product Characteristics can be found at: www.vmd.defra.gov.uk/productinformationdatabase/search.aspx

References:

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5. Pet food manufacturing association, Pet population statistics 2016. <http://www.pfma.org.uk/pet-population-2016>
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- † Extrapolation from total UK cat population as stated by the 2016 PFMA report.


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HYPERTHYROIDISM...

...complex problem,
simple solution.



 **Thyronorm**[®]

The **ONLY ORAL LIQUID** therapy
for the management of hyperthyroidism


Norbrook[®]



Thyronorm[®]

5mg/ml THIAMAZOLE



Tried and trusted active ingredient in a novel formula for ease of use and increased compliance



Liquid thiamazole solution for easy dose titration	Clearly marked easy to use syringe
Available in 30ml and 100ml bottles	For the long term treatment of feline hyperthyroidism and the stabilisation of hyperthyroidism in cats prior to surgical thyroidectomy.
Honey flavoured for improved acceptability	

HYPERTHYROIDISM...

...said to affect 10% of the cat population over the age of nine¹, or 2-3% of the total feline population² (~225k cats¹).

95% of those diagnosed are 10-13 years; only 5% of cats are younger than 10 years at time of diagnosis³. Therefore concurrent disease is often present.

Early diagnosis and management of hyperthyroidism can help with the identification and appropriate treatment of other concurrent conditions, such as systemic hypertension and chronic kidney disease.



Clinical signs

Well established in cats, with loss of muscle mass, polyphagia combined with weight loss, behavioural changes and increased heart rate / arrhythmia being very common^{1,2,6}.

Cats with hyperthyroidism are susceptible to stress-induced worsening of clinical signs - it is important to treat them gently and sensitively.

Diagnosis

The correct signalment (age, sex, breed), characteristic clinical signs and high concentrations of total thyroxine (tT4) are extremely specific for diagnosis of hyperthyroidism in cats³.

Treatment

The aim of treating hyperthyroidism in cats should be to achieve the lowest possible dose rate, and the dose should be titrated to effect according to the total T4 and clinical response to treatment⁷.



5 mg/ml Oral Solution for Cats

Contains 5mg/ml thiamazole (also known as methimazole)

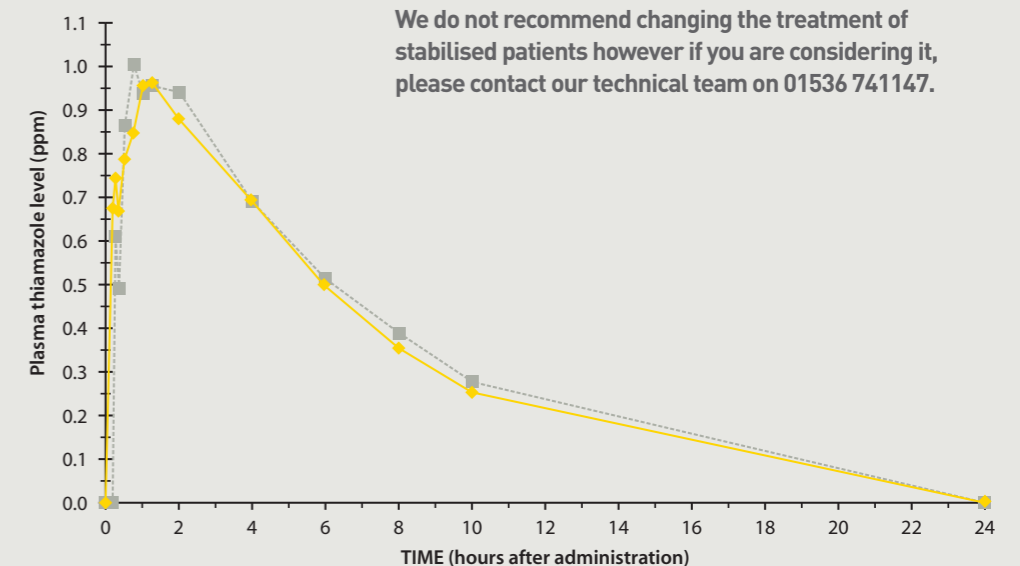
The easy to use liquid alternative to tablets, for owners who have difficulty treating their cat.

87.4% of owners preferred using liquids for long term medication of their cats⁴.

Proven *in-vivo* bioequivalence to thiamazole/methimazole containing tablets

Figure 1: Mean plasma levels of thiamazole (ppm) in cats following oral administration at a dose rate of 5 mg thiamazole/animal on one occasion

—●— Mean of Thyronorm[®] 5 mg/ml Oral Solution for Cats
 - -■- - Mean of methimazole 5 mg coated tablets for cats



- Initial starting dose 5mg active ingredient per day, ideally split into two doses
 - 12 hour interval between doses will provide optimum stabilisation for most cats
 - In order to enhance stabilisation of the hyperthyroid patient the same dosing schedule relative to feeding should be used daily
 - Liquid formulation enables precise control and simple dose titration
 - A stress free treatment regime at home will be beneficial to the cat's welfare and the pet owner bond
 - Added honey flavouring to maximise palatability and acceptance
 - Clearly marked dosing syringe; the syringe is marked in milligrams of active ingredient (thiamazole) to ensure accurate dosing depending on tT4 testing results
 - Testing: 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
 - In use shelf life: 6 months from first opening
 - By enabling particularly small dose adjustments, cats with mild hyperthyroidism and concurrent renal dysfunction (based on a risk: benefit assessment) can have their conditions easily and precisely controlled with Thyronorm
- We do not recommend changing the treatment of stabilised patients however if you are considering it, please contact our technical team on 01536 741147.**