

PRESCRIPTION ANIMAL REMEDY

KEEP OUT OF REACH OF CHILDREN

FOR ANIMAL TREATMENT ONLY

READ SAFETY DIRECTIONS BEFORE OPENING
OR USING

THYRONORM® ORAL SOLUTION FOR CATS

5 mg/mL Thiamazole

For use by or under direction of a veterinarian

Indications

Thyronorm Oral Solution for Cats is indicated for both the stabilisation of hyperthyroidism in cats prior to surgical thyroidectomy and for the long-term treatment of feline hyperthyroidism.

Net Contents:
30 mL
100 mL

DIRECTIONS FOR USE

Use as directed by prescribing veterinarian

Contraindications

Do not use in cats suffering from concurrent systemic diseases such as severe primary 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 neutropaenia and lymphopaenia. Symptoms may include lethargy and increased susceptibility to infection.

Do not use in animals with platelet disorders and coagulopathies (particularly thrombocytopaenia). Symptoms may include bruising and excessive bleeding from wounds.

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.

Precautions

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.

Do not administer in food as efficacy of the product when administered via this route has not been established.

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.

For veterinarians contemplating a once daily dosing regime it should be noted that efficacy studies were conducted using only a twice daily dosing regime. Consequently, the efficacy of once daily dosage has not been established. Therefore, if once daily dose of 5 mg is required to facilitate compliance, reduced efficacy may occur.

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

Side Effects (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 adverse reactions/side effects including thrombocytopaenia 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
- inappetence/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, neutropaenia, lymphopaenia, slight leucopaenia, agranulocytosis, thrombocytopaenia or haemolytic anaemia).

These side effects resolve within 7 - 45 days after cessation of thiamazole therapy. If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

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 neutropaenia, lymphopaenia, 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.

If overdose occurs, stop treatment and give symptomatic and supportive care.

Dosage and Administration

In use shelf life: Use the contents within 6 months of first breaching the container. Discard the unused portion. For oral use only. This product should be administered directly into the mouth of the cat. Use only the syringe provided with mg (milligram) markings. The recommended starting dose is 5 mg per day and the total daily dose should be divided into two 2.5 mg doses administered morning and night. In order to enhance stabilisation of the hyperthyroid patient, the same dosing schedule with regards 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 veterinarians: 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. In cats that require particularly small dose adjustments, increments of 1.25 mg 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 per day is required animals should be monitored particularly carefully. The dose administered should not exceed 20 mg per day.

Advice on correct administration: Follow the dosing instructions and duration of treatment advised by the veterinary surgeon.

General Directions

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 they are febrile (have a high temperature), they 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 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 leucopaenia 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. Neutropaenic animals (neutrophil counts $<2.5 \times 10^9/L$) should be treated with prophylactic bactericidal antibacterial drugs and supportive therapy. As thiamazole can cause haemoconcentration, cats should always have access to drinking water.

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.

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.

Safety Directions

Wash hands with soap and water after administration of the product and handling the vomit or of litter used by treated animals.

Warning - may cause birth defects.

First Aid

If poisoning occurs, contact a doctor or Poisons Information Centre. Phone Australia 13 11 26.

Additional User Safety

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). 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 or of 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. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician. 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 may cause harm to the unborn child, 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.

Disposal

Dispose of container by wrapping with paper and putting in garbage.

Storage

Store below 30 °C (room temperature). Do not freeze.

Presentation

Thyronorm Oral Solution for Cats is available in 30 and 100 mL presentations.

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In New Zealand:

RESTRICTED VETERINARY MEDICINE
Registered pursuant to the ACVM Act 1997,
No A012113
See www.foodsafety.govt.nz for registration conditions.

Registered to and distributed by:
Norbrook NZ Ltd
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Auckland, New Zealand
Ph: 0800 224 022

Warning



Handling Precautions:

Suspected of damaging fertility or the unborn child.

Obtain special instructions before use.

Do not handle until all safety precautions have been read and understood. Wear protective gloves. Store locked up.

First Aid:

For advice contact the National Poisons Centre 0800 POISON (0800 764 766) in New Zealand. Have this product label with you when you call. If exposed or concerned: Get medical attention.

Disposal:

Dispose of product, packaging and waste at an approved landfill or other equivalent facility.