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Thyronorm 5 mg/ml Oral Solution for Cats

Species: Cats

Therapeutic indication:Pharmaceuticals: Hormones and therapeutically related products: Others

Active ingredient: Thiamazole

Product: Thyronorm 5 mg/ml Oral Solution for Cats

Product index: Thyronorm

Incorporating:

Qualitative and quantitative composition

<p Each ml contains:

Active substance(s):

Thiamazole

Excipients:

Qualitative composition of excipients and other constituents	Quantitative composition if that information is es the veterinary medicinal product
Sodium benzoate (E211)	1.5 mg
Glycerol	
Povidone K30	
Xanthan gum	

Disodium phosphate dihydrate

Sodium dihydrogen phosphate dihydrate

Citric acid

Honey flavour

Simethicone emulsion

Purified water

Pharmaceutical form

Oral solution.

An off-white to light yellow opaque solution.

Clinical particulars

Target species

Cats

Indications for use, specifying the target species

For the stabilisation of hyperthyroidism in cats prior to surgical thyroidectomy.

For the long term treatment of feline hyperthyroidism.

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.

Please refer to section, *"Use during pregnancy, lactation or lay"*

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 the veterinary medicinal 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 before initiating treatment and closely afterwards.

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.

Please refer to section, *"Amounts to be administered and administration route" 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 physician.

This the veterinary medicinal 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 the veterinary medicinal 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 the veterinary medicinal 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 the veterinary medicinal 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 the veterinary medicinal product or handle the litter/vomit of treated cats.

Special precautions for the protection of the environment:

Not applicable

Adverse reactions (frequency and seriousness)

Cats:

Uncommon (1 to 10 animals / 1,000 animals treated):	Vomiting1 ; Anorexia1 , Inappetence1 , Lethargy1 Pruritus1, 2, Excoriatic Icterus1, 4, Hepatopathy1 ; Eosinophilia1 , Lymphocytosis1 , Neutroper Leucopenia1 (slight), Agranulocytosis1 Thrombocytopenia1, 5, 6, Haem
Rare (1 to 10 animals / 10,000 animals treated):	Autoimmune disorder (serum anti-nuclear antibodies)5,7 .
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Lymphadenopathy5,7, Anaemia5,7 .

1 Resolves within 7-45 days after cessation of thiamazole therapy.
2 Severe and of the head and neck.
3 Sign of a bleeding diathesis.
4 Associated with hepatopathy.
5 Immunological side effect.
6 Occurs uncommonly as a haematological abnormality and rarely as an immunological side effect.
7 Treatment should be stopped immediately and alternative therapy considered following a suitable period for recovery.

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.

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.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Use during pregnancy, lactation or lay

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. Do not use during the whole of the pregnancy and 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

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.

Amounts to be administered and administration route

For oral use only.

The veterinary medicinal product should be administered directly into the mouth of the cat, using the measuring syringe.

The syringe is graduated in 0.5 mg up to 5 mg.

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

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 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.

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 1.25mg 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 10mg of thiamazole per day is required animals should be monitored particularly carefully.

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

For long-term treatment of hyperthyroidism, the animal should be treated for life.

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 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 Section, *"Adverse reactions"*.

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

Withdrawal period(s)

Not applicable

Pharmacological particulars

Pharmacotherapeutic group: antithyroid preparations: sulphur-containing imidazole derivatives.

ATCvet code: QH03BB02

Pharmacodynamic properties

Thiamazole acts by blocking the biosynthesis of thyroid hormone *in vivo*. The primary action is to inhibit binding of iodide to the enzyme thyroid peroxidase, thereby preventing the catalysed iodination of thyroglobulin and T3 and T4 synthesis.

Pharmacokinetic particulars

Following oral dosing with the veterinary medicinal product in healthy cats, at a dose rate of 5 mg, thiamazole is rapidly and completely absorbed. Elimination of the drug from cat plasma is rapid with a half-life of 4.35 hours. The time of peak plasma levels occurs 1.14 hours after dosing. Cmax is 1.13 µg/ml.

In rats thiamazole has been shown to be poorly bound to plasma protein (5%); 40% was bound to red blood cells. The metabolism of thiamazole in cats has not been investigated, however, in rats thiamazole is rapidly metabolised in the thyroid gland. About 64% of the administered dose being eliminated in the urine and only 7.8% excreted in faeces. This is in contrast with man where the liver is important for the metabolic degradation of the compound. The drug residence time in the thyroid gland is assumed to be longer than in the plasma.

Pharmaceutical particulars

Major incompatibilities

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

Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years

Shelf life after first opening the immediate packaging: 6 months

Special precautions for storage

Keep the container tightly closed.

This veterinary medicinal product does not require any special temperature storage conditions.

Nature and composition of immediate packaging

Cardboard box with 30 ml and 100 ml presentations filled into amber polyethylene terephthalate (PET) screw bottles with HDPE/LDPE child resistant caps.

The veterinary medicinal product is supplied with a 1 ml polyethylene/polypropylene measuring syringe. The syringe is graduated in 0.5 mg increments up to 5 mg.

Not all pack sizes may be marketed.

Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Marketing Authorisation Holder (if different from distributor)

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

Marketing Authorisation Number

Vm 02000/4399

Significant changes

Date of the first authorisation or date of renewal

03 June 2016

Date of revision of the text

February 2025

Any other information

Nil.

Legal category

Legal category:POM-V

GTIN

GTIN description: Thyronorm 5 mg/ml Oral Solution for Cats - 30ml

GTIN:5023534037453

GTIN description: Thyronorm 5 mg/ml Oral Solution for Cats - 100ml

GTIN:502353403746