thiafeline® 2.5mg

Film-coated tablets for cats

Thiamazole

Statement of the active substances and other ingredients

Description:

Each pink film-coated, biconvex tablet (5.5mm diameter) contains thiamazole 2.5mg.

Indications

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.

Do not use in cats with hypersensitivity to thiamazole or the excipient, polyethylene glycol.

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 reported include vomiting, inappetance/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 resolved 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.

Target species

Cats

Dosage for each species, route and method of administration

Administration route

Oral.

Amounts to be administered

For the stabilisation of feline hyperthyroidism prior to surgical thyroidectomy and for the long term treatment of feline hyperthyroidism, the recommended starting dose is 5mg per day.

Wherever possible, the total daily dose should be divided into two and administered morning and evening. Tablets should not be split.

If, for reasons of compliance, once daily dosing with a 5mg tablet is preferable, then this is acceptable although the 2.5mg tablet given twice daily may be more efficacious in the short term. The 5mg tablet is also suitable for cats requiring higher dose rates.

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. Dose adjustments should be made in increments of 2.5mg and the aim should be to achieve the lowest possible dose rate.

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

The dose administered should not exceed 20mg/day.

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

Special storage precautions

Keep out of the reach and sight of children.

Keep the container in the outer package in order to protect from light.

Do not use after the expiry date which is stated on the blister and carton after "EXP".

Special warnings

Special warnings for the target species

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

Special precautions for use in animals

If more than 10mg 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 10^9/l) should be treated with prophylactic bactericidal antibacterial drugs and supportive therapy.

User Warnings

Wash hands after use.

In the case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Thiamazole may cause vomiting, epigastric distress, headache, fever, arthralgia, pruritus and pancytopaenia. Treatment is symptomatic.

Wash hands with soap and water after handling litter used by treated animals.

Do not eat, drink or smoke while handling the tablet or used litter.

Do not handle this product if you are allergic to anti-thyroid products. 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. Do not break or crush tablets.

As thiamazole is a suspected human teratogen, women of child-bearing age and pregnant should wear gloves when handling litter of treated cats.

Pregnant women should wear gloves when handling this product.

Use during pregnancy and lactation

Laboratory studies in rats and mice have shown evidence of teratogenic and embryotoxic effects of thiamazole. The safety of the product was not assessed in pregnant or lactating cats. Do not use in pregnant or lactating females.

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 30mg/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 30mg/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 20mg 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 Adverse reactions section.

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

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.

Special precautions for the disposal of unused product or waste material, if any

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Medicines should not be disposed of via wastewater or household waste.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

Date on which the package leaflet was last approved: 29.05.13

Other information

For animal treatment only.

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

Absorption

Following oral dosing in healthy cats, thiamazole is rapidly and completely absorbed with a bioavailability of >75%. However, there is a considerable variation between animals.

Peak plasma levels occur approximately 0.5-1 hour after dosing (Tmax = 0.69h). Cmax is between 1.1 and 2.7µg/ml (1.78µg/ml) and half-life is 3.3h.

Distribution

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.

The drug residence time in the thyroid gland is assumed to be longer than in the plasma.

Metabolism and elimination

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.

Pack sizes

30 tablets in a cardboard carton containing 1 aluminium/pvc strips each strip with 30 tablets.

60 tablets in a cardboard carton containing 2 aluminium/pvc strips each strip with 30 tablets.

120 tablets in a cardboard carton containing 4 aluminium/pvc strips each strip with 30 tablets.

150 tablets in a cardboard carton containing 5 aluminium/pvc strips each strip with 30 tablets.

300 tablets in a cardboard carton containing 10 aluminium/pvc strips each strip with 30 tablets.

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.

Marketing Authorisation Holder:
Le Vet Beheer B.V., Wilgenweg 7, 3421 TV Oudewater, The Netherlands

Manufacturer for the batch release:
Lindopharm GmbH, Neustrasse 82, D-40721 Hilden, Germany

Distributed by:
Animalcare Ltd, 10 Great North Way, York, YO26 6RB, UK

UK only:
Vm 41821/4005
POM-V
To be supplied only on veterinary prescription

IE only:
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