RESTRICTED VETERINARY MEDICINE
Keep out of the reach of children
FOR ANIMAL TREATMENT ONLY

VIDALTA®

Tablets for cats

Vidalta 10mg & 15mg are round pink tablets, each containing 10mg or 15 mg carbimazole and 0.25 mg red ferric oxide (E 172).

Read entire carton and leaflet before use

INDICATIONS

For the treatment of hyperthyroidism and hyperthyroidism-associated clinical signs in cats.

DOSAGE AND ADMINISTRATION

For oral use only.
Vidalta tablets should be administered at the same time every day, in particular with relation to feeding.
Do not break or crush Vidalta tablets as this will affect the sustained release properties of the tablet.
The prolonged release formulation of Vidalta enables a 24 hour dosing interval.
The aim of treatment is to maintain total thyroxin concentrations (TT4) in the lower end of the reference range. Accordingly, the following dose recommendations for dosing during adjustment and maintenance phases are suggested. However dosing adjustment should be primarily based upon the clinical assessment of the individual cat. Monitoring of TT4, full haematology and liver and kidney parameters is advised at each recommended follow up visit.

Adjustment phase
The starting dose is a single daily oral administration of one tablet of **VIDALTA 15 mg** (15mg carbimazole) per cat. Consideration could be given to a starting dose of Vidalta 10 mg daily where the TT4 concentration is only mildly increased, e.g. between 50 nmol/L and 100 nmol/L. With the recommended starting dose of one Vidalta 15 mg tablet once daily, total thyroxin concentration (TT4) may decrease to within the euthyroid range (TT4<50 nmol/L) shortly after treatment initiation. A dose adjustment may be required as early as 10 days after commencing treatment. Dose adjustment should be also performed 3, 5 and 8 weeks after initiation of treatment, depending on both clinical and hormonal responses to treatment.

Maintenance phase
Follow-up visits every 3 to 6 months are recommended. The dose should be adjusted individually based on clinical signs and total thyroxin concentration (TT4). It is advisable to check TT4 10-14 days after dose adjustment. The therapeutic dose of Vidalta ranges between 10 mg (one 10 mg tablet) and 25 mg (one 10 mg tablet and one 15 mg tablet) once daily. Some cats require doses of less than 10 mg carbimazole daily. Every other day dosing with 10 mg or 15 mg of carbimazole may be sufficient to control the disease. Dose increases should not be made in increments of greater than 5 mg. Doses above 20 mg have only been trialled in a small number of cats and should be used with caution.

CONTRADICTIONS

Do not use in cats with haematological disorders such as anaemia, neutropenia; lymphopenia, or thrombocytopenia. Do not use in cats with coagulopathies. Do not use in pregnant or lactating queens. Do not use in cats with hypersensitivity to mercaptoimidazoles (carbimazole or methimazole).

PRECAUTIONS

Methimazole, the active metabolite of carbimazole, inhibits thyroid hormone production and therefore cessation of treatment with carbimazole will result in a rapid (within 48 hours) return to pre-treatment thyroid hormone levels. Chronic administration is therefore necessary unless surgical or radiation-induced thyroidectomy is performed.
A small proportion of cats with thyroid adenoma may fail to respond or have a poor response to treatment.
Thyroid carcinoma is a rare cause of hyperthyroidism in the cat and medical management alone is not recommended in such cases as it is not curative.
The safety of the veterinary medicinal product has not been established in pregnant or lactating queens. However, since methimazole crosses the placenta, distributes into milk and reaches approximately the same concentration as in maternal serum, the product should not be used in pregnant or lactating queens.
Concomitant treatment with phenobarbitone may reduce the clinical efficacy of carbimazole.
The concomitant use of benzimidazole anthelmintics (fenbendazole or mebendazole) has been shown to reduce the hepatic oxidation of this therapeutic class and may therefore induce an increase of their circulating rates. Accordingly, co-administration of carbimazole with a benzimidazole is not recommended. Methimazole may display immunomodulating properties. This should be taken into account when considering vaccination of the cat.
In case of overdosage, adverse effects that may appear include, but are not limited to: weight loss, inappetence, vomiting and lethargy. Coat and skin abnormalities (erythema, alopecia), as well as haematological/biochemical changes (eosinophilia, lymphocytosis, neutropenia, lymphopenia, slight leukopenia, agranulocytosis, thrombocytopenia or haemolytic anaemia) may also appear. Hepatitis and nephritis have been reported. These adverse effects may become severe in case of chronic overdosing. In most cases, adverse effects are reversible upon treatment discontinuation and appropriate veterinary care.
Total thyroxin concentrations (TT4) below the lower limit of the reference range may be observed during treatment although this is rarely linked to overt clinical signs. Decreasing the dose will lead to an increase of the TT4. Dose adjustment should not be made based on TT4 only.

ADVERSE EFFECTS

Most frequent common adverse reactions encompass vomiting, diarrhoea, reduced appetite, loss of condition, lethargy, tachycardia, polydipsia, dehydration, and polyuria. Dermatological signs (pruritus, moist dermatitis, erythema, alopecia) have also been reported. These clinical signs are usually mild, adequately controlled by symptomatic therapy and do not require treatment discontinuation. Weight loss, dyspnoea, aggressiveness, disorientation, ataxia or pyrexia have also been reported in rare cases
Treatment of hyperthyroidism may result in a reduction in the glomerular filtration rate. This can lead to unmasking of pre-existent renal dysfunction. Renal function should therefore be monitored (BUN and creatinine) before and during treatment, preferably at each visit of the dose adjustment and maintenance phases. The dose should be adjusted according to the risk assessment for the individual case.
Treatment of hyperthyroidism with carbimazole may also induce an elevation of liver enzymes (ALKP and ALT) or a worsening of pre-existing hepatic disorders. Liver enzymes should therefore be monitored before and during treatment, preferably at each visit of the dose adjustment and maintenance phases. Severe cases may require temporary or permanent treatment discontinuation. Liver enzyme elevations are usually reversible following drug discontinuation, although symptomatic therapy (nutritional and fluid support) may be required.
Anaemia, increase or decrease in white blood cell count, neutrophilia, thrombocytopenia, eosinophilia and/or lymphopenia may also occur, in particular during the first 4-6 weeks of treatment. Haematology parameters should therefore be monitored on a regular basis before and during treatment, preferably at each visit of the dose adjustment phase and maintenance phase. Treatment discontinuation may be required in case of persistent and marked disorder. In most of the cases, the abnormality will resolve spontaneously within 1 month after treatment discontinuation. Positive antinuclear antibody titres have also been reported. If you notice any serious effects or other effects not mentioned in this leaflet, please talk to your veterinarian.

SIDE EFFECTS
Treatment of hyperthyroidism may result in a reduction in the glomerular filtration rate. This can lead to unmasking of pre-existent renal dysfunction. Treatment of hyperthyroidism may also induce an elevation of liver enzymes or a worsening of pre-existing hepatic disorders. Renal and liver function should therefore be monitored before and during treatment.
Treatment should be adjusted according to the risk assessment for the individual case.
Doses above 20 mg have only been trialled in a small number of cats. Adverse reactions may occur at this dose, therefore careful monitoring is recommended and the dose should be adjusted according to the risk assessment for the individual case.

SAFETY DIRECTIONS
Vidalta should be used for oral treatment of cats only. Wash hands with soap and water after handling the tablet or 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 hyperthyroidism inhibitors. As carbimazole is a suspected human teratogen, women of child-bearing age should wear gloves when handling litter and/or vomit of treated cats.
In the case of accidental ingestion, seek medical advice immediately and show the package insert or the label to the doctor.
See Safety Data Sheet for further information. www.msd-animal-health.co.nz

FIRST AID
If swallowed do not induce vomiting. If exposed or concerned get medical advice.

DISPOSAL Dispose of used packaging in household rubbish or recycle. Unused tablets should be returned to a veterinary clinic.

STORAGE
Store below 25°C. Protect from humidity and light. Keep the plastic container tightly closed to protect from moisture. Do not remove the desiccant.

ACVM Registration No: A10622. See www.foodsafety.govt.nz for registration conditions.
Approved Pursuant to the HSNO Act 1996, HSR100532 & HSR100533. See www.epa.govt.nz for controls.

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Schering-Plough Animal Health Ltd
Phone: 0800 800 543
www.msd-animal-health.co.nz

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