

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vidalta 10 mg prolonged-release tablets for cats

Carbimazole

2. STATEMENT OF ACTIVE SUBSTANCES

10 mg carbimazole per tablet.
Red ferric oxide (E172).

3. PHARMACEUTICAL FORM

Prolonged-release tablet.

4. PACKAGE SIZE

30 tablets
100 tablets
6 x 30 tablets
6 x 100 tablets

5. TARGET SPECIES

Cats.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use.

Do not break or crush Vidalta tablets as this will affect the sustained release property.

10. EXPIRY DATE

EXP {month/year}

Once opened, use within 100 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.

Store in the original container.

Keep the container tightly closed to protect from moisture.

Do not remove the desiccant.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of waste material in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive,
Magna Business Park,
Citywest
Road,
Dublin 24, Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4529

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vidalta 10 mg prolonged-release tablets for cats
Carbimazole

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

10 mg carbimazole per tablet

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

30 tablets
100 tablets

4. ROUTE(S) OF ADMINISTRATION

Oral use.

5. WITHDRAWAL PERIOD(S)

Not applicable

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use within 100 days.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

Vidalta 10 mg prolonged-release tablet for cats

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:

Intervet GesmbH
Siemensstrasse 107
1210 Vienna
Austria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vidalta 10 mg prolonged-release tablet for cats
Carbimazole

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Vidalta is presented as round pink tablets with little spots each containing 10.0 mg carbimazole (active ingredient) and 0.25 mg red ferric oxide (E 172, excipient).

4. INDICATION(S)

Treatment of hyperthyroidism and hyperthyroidism-associated clinical signs.

5. 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 auto-immune diseases and/or altered red or white blood cell, such as anaemia, neutropaenia or lymphopaenia.

Do not use in cats with platelet disorders (particularly thrombocytopaenia) or coagulopathies.

Do not use in cats with hypersensitivity to mercaptoimidazoles such as carbimazole or thiamazole (methimazole) or to any of the excipients.

6. ADVERSE REACTIONS

Treatment of hyperthyroidism may result in a reduction of renal perfusion. Azotaemia has been reported in rare cases; depending on the severity, temporary or permanent discontinuation of treatment may be required. Polyuria and polydipsia have also been reported in rare (polydipsia) or very rare (polyuria) cases.

Weight loss, vomiting, lethargy, tachycardia, reduced appetite, diarrhoea and dehydration have been observed in rare cases.

Increased liver enzymes have been reported in rare cases. Severe cases may require temporary or permanent discontinuation of treatment. However, these elevations are usually reversible when treatment is discontinued, although symptomatic therapy (nutritional and fluid support) may be required.

Anaemia, increase or decrease in white blood cell count, neutrophilia, thrombocytopaenia, eosinophilia and/or lymphopaenia have been reported in rare cases, in particular during the first 4 – 6 weeks of treatment. Discontinuation of treatment may be required in case of persistent and marked disorder. In most cases, the abnormality will resolve spontaneously within 1 month after the treatment has been discontinued.

Dermatological signs (pruritus, dermatitis, erythema, alopecia) have been reported in rare cases. These clinical signs are usually mild, adequately controlled by symptomatic therapy and do not require discontinuation of treatment. However, if more severe clinical signs occur that do not respond to symptomatic therapy, the dose should be reduced or treatment stopped following a benefit-risk assessment by the responsible veterinarian.

Signs of gastrointestinal bleeding such as bloody vomit, oral haemorrhage or dark faeces have been reported in rare cases.

Ataxia, pyrexia, dyspnoea, disorientation, aggressiveness, and positive antinuclear antibody have been reported in very rare cases.

In cases of serious adverse reactions, mortality, possibly due to the product, might occur if treatment is not discontinued. In many cases adverse reactions are reversible on cessation of treatment.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reactions)
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any serious effects or other effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cats.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The aim of treatment is to maintain total thyroxine concentrations (TT_4) in the lower end of the reference range. The following dose recommendations during adjustment and maintenance phases are suggested, but any adjustment should primarily be based on the clinical assessment of the individual cat. Monitoring TT_4 levels, full haematology and liver and kidney parameters is recommended at each follow-up visit.

Adjustment phase

The starting dose is a single daily oral administration of one tablet of 15 mg carbimazole per cat. Consideration could be given to a starting dose of one 10 mg tablet daily where the TT_4 concentration is only mildly increased, e.g. between 50 nmol/L and 100 nmol/L.

With the recommended starting dose of one 15 mg tablet once daily, TT_4 may decrease to within the euthyroid range ($TT_4 < 50$ nmol/L) shortly after treatment initiation. A dose adjustment may be required as early as 10 days of 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 TT_4 . It is advisable to check TT_4 10 – 14 days after dose adjustment.

The therapeutic dose 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.

9. ADVICE ON CORRECT ADMINISTRATION

For oral use only.

Administration with food enhances bioavailability. The timing of treatment and its relation to feeding should be kept consistent from day to day.

Do not break or crush Vidalta tablets as this will affect the sustained release property.

10. WITHDRAWAL PERIOD(S)

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C.

Store in the original container.

Keep the container tightly closed to protect from moisture.

Do not remove the desiccant.

Do not use this veterinary medicinal product after the expiry date stated on the container. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate packaging: 100 days.

12. SPECIAL WARNING(S)

Special warnings for each target species

Thiamazole (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.

Special precautions for use in animals

Treatment should be adjusted following a benefit-risk assessment by the responsible veterinarian in each individual case.

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.

Due to risk of leucopaenia or haemolytic anaemia, haematology parameters should be monitored on a regular basis before and during treatment, preferably at each visit of the dose adjustment phase and maintenance phase.

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 x 10⁹/L) should be treated prophylactically with bactericidal antibiotics and supportive therapy.

Doses above 20 mg have only been trialled in a small number of cats and should be used with caution.

Therefore, careful monitoring is recommended and the dose should be adjusted in individual cases following a benefit-risk assessment by the responsible veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Vidalta should be used for oral treatment of cats only. Wash hands with soap and water after use and when handling litter used by treated animals.

Do not handle this product if you are allergic to antithyroid products. If allergic symptoms develop, such as 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.

As carbimazole is a suspected human teratogen, women of child-bearing age should wear gloves when handling litter or vomit of treated cats.

Pregnant women should wear gloves when handling the product.

Do not break or crush tablets.

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

In the case of accidental ingestion, seek medical advice immediately and show the package insert or the label to the physician. Carbimazole, as a prodrug of thiamazole (methimazole), may cause vomiting, epigastric distress, headache, fever, arthralgia, pruritus and pancytopenia. Treatment is symptomatic.

Pregnancy and lactation

Laboratory studies in rats and mice have shown evidence of teratogenic and embryotoxic effects of thiamazole (methimazole).

The safety of the product was not assessed in pregnant or lactating cats.

Furthermore, thiamazole crosses the placenta, distributes into milk and reaches approximately the same concentration as in maternal serum.

Do not use in pregnant or lactating females.

Interaction with other medicinal products and other forms of interaction

Concomitant treatment with phenobarbital 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.

Thiamazole (methimazole) may display immunomodulating properties. This should be taken into account when considering vaccination of the cat.

Overdose (symptoms, emergency procedures, antidotes)

In case of an overdose, adverse effects that may appear include, but are not limited to, weight loss, inappetence, vomiting, lethargy and less frequently signs of gastrointestinal bleeding such as haematemesis, oral haemorrhage, or haemorrhage of the intestinal tract. Coat and skin abnormalities (erythema, alopecia), as well as haematological/biochemical changes (eosinophilia, lymphocytosis, neutropenia, lymphopenia, slight leucopenia, 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.

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.

See also section 6.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Medicines should not be disposed of via wastewater. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

The prolonged release formulation of Vidalta enables a 24 hour dosing interval.

Pack sizes:

Plastic container containing 30 or 100 tablets.

Six plastic containers containing 30 or 100 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.

For animal treatment only.

Vm 01708/4529

POM-V

To be supplied only on veterinary prescription.

Distributor in Northern Ireland:

Intervet Ireland Ltd.

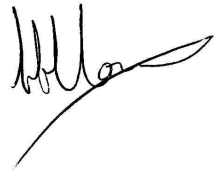
Magna Drive,

Magna Business Park,

Citywest Road,

Dublin 24, Ireland

Revised: August 2020
AN: 00299/2020

A handwritten signature in black ink, consisting of several vertical strokes followed by a long, sweeping horizontal stroke that curves downwards to the right.

Approved 14 August 2020