PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vidalta 15 mg prolonged-release tablets

2. STATEMENT OF ACTIVE SUBSTANCES

15 mg carbimazole per prolonged-release tablet.

3. PACKAGE SIZE

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

4. TARGET SPECIES

Cats.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

EXP. {mm/yyyy}
Once opened, use within 100 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Store in the original container.
Protect from light.
Store in a dry place.
Keep the container tightly closed to protect from moisture.
Do not remove the desiccant.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/5041

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
Bottle-LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vidalta

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

15 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use within 100 days.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Vidalta 15 mg prolonged-release tablet for cats

2. Composition

Each prolonged-release tablet contains:

Active substance:
Carbimazole 15.0 mg

Excipients:
Red ferric oxide (E172) 0.75 mg

Round, dark pink tablets with little spots.

3. Target species

Cats**.**

4. Indications for use

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, neutropenia or lymphopenia.
Do not use in cats with platelet disorders (particularly thrombocytopenia) or coagulopathies.
Do not use in cats with hypersensitivity to mercaptoimidazoles such as carbimazole or thiamazole (methimazole) or to any of the excipients.
Please refer to section ‘Pregnancy and lactation’.

6. Special warnings

Special warnings:
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 safe use in the target species:
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 leucopenia 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. Neutropenic animals (neutrophil counts < 2.5 x 10^9/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:
Wash hands with soap and water after use and when handling litter used by treated animals.
Do not handle this veterinary medicinal product if you are allergic to antithyroid veterinary medicinal products. If allergic symptoms develop, such as a skin rash, swelling of the face, lips or eyes or difficulty in breathing, seek medical advice immediately and show the package leaflet or label to the physician.
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 veterinary medicinal 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 leaflet 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 veterinary medicinal 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:
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.
TT_4 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 TT_4. Dose adjustment should not be made based on TT_4 only.

See also section 7.

7. Adverse events

Cats:

Rare (1 to 10 animals / 10,000 animals treated):	Tachycardia (rapid heart rate); Vomiting, Diarrhoea, Blood in vomit, Oral haemorrhage, Blood in faeces; Azotaemia[1], Elevated liver enzymes[2], Anaemia[3], Neutrophilia (increased numbers of neutrophils)[3], Thrombocytopenia (low amounts of platelets)[3], Lymphopenia[3], Eosinophilia[3]; Ataxia (incoordination); Pruritus (itching)[4], Dermatitis (skin inflammation)[4], Erythema (redness)[4], Alopecia (hair loss)[4]; Weight loss, Lethargy, Decreased appetite, Pyrexia (fever), Polydipsia (increased thirst), Dehydration;
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Disorientation; Polyuria (increased urination), Renal vascular disorder[5]; Aggression; Dyspnoea (difficulty breathing); Other abnormal test result[6].

[1] Depending on the severity, temporary or permanent discontinuation of treatment may be required.

[2] Severe cases may require temporary or permanent discontinuation of treatment. These elevations are usually reversible when treatment is discontinued, although symptomatic therapy (nutritional and fluid support) may be required.

[3] May occur 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.

[4] 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.

[5] Treatment of hyperthyroidism may result in a reduction of renal perfusion.

[6] Positive antinuclear antibody (ANA).

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

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. Dosage for each species, routes 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

Oral use.
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 the veterinary medicinal product tablets as this will affect the sustained release property.

10. Withdrawal periods

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.
Protect from light.
Store in a dry place.
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 which is stated on the container after Exp. The expiry date refers to the last day of that month.
Shelf life after first opening the immediate packaging: 100 days.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 06376/5041

Plastic container containing 30 or 100 tablets.
Six plastic containers containing 30 or 100 tablets.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxmeer
Netherlands

Manufacturer responsible for batch release:
Intervet GesmbH
Siemensstrasse 107
1210 Vienna
Austria

Approved 25 March 2025
Gavin Hall