ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vidalta 10 mg prolonged-release tablets for cats
BE, NO: Vidalta Vet 10 mg prolonged release tablets for cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each prolonged-release tablet contains:

Active substance:
Carbimazole 10.0 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Hypromellose	
Microcrystalline cellulose	
Red ferric oxide (E172)	0.25 mg
Silica, colloidal anhydrous	
Magnesium stearate	
Talc	

Round, pink tablet with little spots.

3. CLINICAL INFORMATION

3.1 Target species

Cats.

3.2 Indications for use for each target species

Treatment of hyperthyroidism and hyperthyroidism-associated clinical signs.

3.3 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 counts, such as anaemia, neutropoenia 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 3.7.

3.4 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Treatment should be adjusted according to 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 (see section 3.9).
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 $<2.5 \times 10^9$/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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cats:

Rare (1 to 10 animals / 10,000 animals treated):	Tachycardia; Vomiting, Diarrhoea, Blood in vomit, Oral haemorrhage, Blood in faeces; Azotaemia[1], Elevated liver enzymes[2], Anaemia[3], Neutrophilia[3], Thrombocytopenia[3], Lymphopenia[3], Eosinophilia[3]; Ataxia; Pruritus[4], Dermatitis[4], Erythema[4], Alopecia[4]; Weight loss, Lethargy, Decreased appetite, Pyrexia, Polydipsia, Dehydration;
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Disorientation; Polyuria, Renal vascular disorder[5]; Aggression; Dyspnoea; 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

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 animals.

3.8 Interaction with other medicinal products and other forms of interaction

Concomitant treatment with phenobarbital may reduce the clinical efficacy of carbimazole.
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 in circulating levels. 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.

3.9 Administration routes and dosage

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.

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 the adjustment and maintenance phases are suggested.
Dosing adjustment should primarily be based upon a clinical assessment of the individual cat.
Monitoring of TT_4, full haematology and liver and kidney parameters is recommended at each follow up visit (see sections 3.5 and 3.6).

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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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.

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 section 3.9).

Please also refer to section 3.6.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Not applicable.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QH03BB01

4.2 Pharmacodynamics

Carbimazole is the prodrug of thiamazole (methimazole). Although carbimazole has inherent antithyroid activity, it is almost totally converted to thiamazole soon after its oral administration *in vivo* in humans and cats.
Thiamazole results in dose-dependent inhibition of the thyroid peroxidase-catalysed reactions involved in thyroid hormone synthesis, including oxidation of iodide and iodination of tyrosyl residues in thyroglobulin, thereby inhibiting neosynthesis of thyroid hormones. Thiamazole also interferes with the coupling of iodotyrosines to iodothyronines via inhibition of thyroid peroxidase or by binding and altering the structure of thyroglobulin, this reaction being more sensitive to inhibition than the formation of iodotyrosines. The inhibitory action of thiamazole is reversible.

Thiamazole does not inhibit the action of thyroid hormones already formed and present in the thyroid glands or bloodstream, or interfere with the effectiveness of administered exogenous thyroid hormone (iatrogenic hyperthyroidism). This explains why the length of the latency period until normalisation of serum concentrations of thyroxine and triiodothyronine, and thus to clinical improvement, differs between individuals.

4.3 Pharmacokinetics

Carbimazole is rapidly absorbed from the gastrointestinal tract after oral administration and hydrolysed in the gastrointestinal tract (or immediately after entering into the circulation) to the active metabolite thiamazole (methimazole). The absolute bioavailability of thiamazole from carbimazole in veterinary medicinal product 15 mg tablets is 88 %.
Following oral administration of one tablet of veterinary medicinal product 10 mg to healthy fasted cats, maximum thiamazole concentrations are observed 3 – 4 hours after administration, with a mean peak concentration of thiamazole of 0.54 – 0.87 µg/ml.
Following oral administration of one tablet of veterinary medicinal product 15 mg to healthy fasted cats, maximum thiamazole concentrations are observed 5 – 7 hours after administration, with a mean peak concentration of thiamazole of 0.72 – 1.13 µg/ml.
For both strengths, the thiamazole concentration/time profile is devoid of pronounced peaks and thiamazole persists in the circulation at least 20 and 24 hours for veterinary medicinal product 10 mg and veterinary medicinal product 15 mg, respectively.
The presence of food in the gastrointestinal tract at the time of administration has been shown to increase the bioavailability of thiamazole. When tablets are administered with food, both C_{max} and AUC_{last} may be increased whereas t_{max} is not expected to change.
No cumulative effects are observed upon repeated administration.
The tissue distribution of mercaptoimidazoles has not been specifically studied in cats but has been fully described in rodents. Thiamazole is mainly concentrated in the thyroid and adrenal glands, and can be found to a lesser extent in the thymus, diaphragm, kidneys, brain, liver, colon, testes, small intestine, stomach and plasma.
Mercaptoimidazoles have also been shown to cross the placental barrier.
In rats, thiamazole is excreted mainly via the urine, and to a lesser extent in the faeces.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after first opening the immediate packaging: 100 days.

5.3 Special precautions for storage

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.

5.4 Nature and composition of immediate packaging

High density polyethylene container of 30 or 100 tablets closed with polypropylene tamper-evident, child-resistant screw cap bearing a desiccant.

Packs of 1 or 6 containers.

Not all pack sizes may be marketed.

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

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

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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

{To be completed nationally, in accordance with SPOR}

7. MARKETING AUTHORISATION NUMBER(S)

{To be completed nationally}

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}
{To be completed nationally}

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{DD/MM/YYYY}
{To be completed nationally}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vidalta 10 mg prolonged-release tablets
BE, NO: Vidalta Vet 10 mg prolonged-release tablets

2. STATEMENT OF ACTIVE SUBSTANCES

10 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

{To be completed nationally, in accordance with SPOR}

14. MARKETING AUTHORISATION NUMBERS

{To be completed nationally}

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Bottle – LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vidalta
BE, NO: Vidalta Vet

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

10 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Vidalta 10 mg prolonged-release tablet for cats
BE, NO: Vidalta Vet 10 mg prolonged-release tablets for cats

2. Composition

Each prolonged-release tablet contains:

Active substance:
Carbimazole 10.0 mg

Excipients:
Red ferric oxide (E172) 0.25 mg

Round, pink tablet 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:
The veterinary medicinal product 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 veterinary medicinal product if you are allergic to antithyroid veterinary medicinal products. If allergic symptoms develop, such as skin rash, swelling of the face, lips or eyes or difficulty in breathing, seek medical attention 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 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 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	Tachycardia (rapid heart rate);

(1 to 10 animals / 10,000 animals treated):	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 or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}

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 or household waste.

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

{< > MA no. to be adjusted nationally}

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

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder <and manufacturer responsible for batch release> <and contact details to report suspected adverse reactions>:
{< > to be adjusted nationally}

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

<Local representatives <and contact details to report suspected adverse reactions>:>
{< > to be adjusted nationally}

<For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.>
{< > to be adjusted nationally}