SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Felidale 2.5 mg Coated Tablets for Cats

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 tablet contains:

Active substance:

Thiamazole	2.5 mg

Excipients:

Titanium Dioxide (E171)	1.12 mg
Erythrosine (E127)	0.01 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Coated tablet.
Pink sugar-coated biconvex tablets, 5.5 mm diameter.

4. CLINICAL PARTICULARS

4.1 Target species

Cats.

4.2 Indications for use, specifying the target species

For the stabilisation of hyperthyroidism in cats prior to surgical thyroidectomy.
For the long-term treatment of feline hyperthyroidism.

4.3 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 neutropaenia and lymphopaenia.
Do not use in animals with platelet disorders and coagulopathies (particularly thrombocytopaenia).
Do not use in cats with hypersensitivity to thiamazole or the excipient, polyethylene glycol.
Do not use in pregnant or lactating females.
Please refer to section 4.7.

4.4 Special warnings for each target species

4.5 Special precautions for use

Special precautions for use in animals

As thiamazole can cause haemoconcentration, cats should always have access to drinking water.
If more than 10 mg 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 leucopaenia 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 $<2.5 \times 10^9$/l) should be treated with prophylactic bactericidal antibacterial drugs and supportive therapy.
Please refer to section 4.9 for monitoring instructions.

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

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 antithyroid 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 women should wear gloves when handling litter of treated cats.
Pregnant women should wear gloves when handling the product.

4.6 Adverse reactions (frequency and seriousness)

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 that are 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, neutropaenia, lymphopaenia, slight leucopenia, agranulocytosis, thrombocytopaenia or haemolytic anaemia). These side effects resolve within 7-45 days after cessation of thiamazole therapy.
Possible immunological side effects include anaemia, with rare side effects including thrombocytopaenia 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.

4.7 Use during pregnancy or 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.

4.8 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.

4.9 Amount(s) to be administered and administration route

For oral administration only.
For the stabilisation of feline hyperthyroidism prior to surgical removal of the thyroid gland, one 2.5 mg tablet morning and evening. This should ensure euthyroidism within 3 weeks in most cases.
For long-term treatment of hyperthyroidism, the starting dose should be 2.5 mg twice daily. After 3 weeks, the dose should be titrated to effect according to the serum total T4. Dose adjustments should be made by increments of 2.5 mg. Wherever possible, the total daily dose should be divided into two and administered morning and evening. Tablets should not be split. The aim should be to achieve the lowest possible dose rate.

If, for reasons of compliance, once daily dosing with a 5 mg tablet is preferable, then this is acceptable although reduced efficacy can be expected compared to a twice daily regime. The 5 mg tablet is also suitable for cats requiring higher dose rates.
If more than 10 mg per day is required animals should be monitored particularly carefully. The dose administered must not exceed 20 mg/day.
For long-term treatment of hyperthyroidism the animal should be treated for life.
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 and the dose titrated as necessary.

4.10 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 30 mg/animal/day: anorexia, vomiting, lethargy, pruritus and haematological and biochemical abnormalities such as neutropaenia, lymphopaenia, reduced serum potassium and phosphorus levels, increased magnesium and creatinine levels and the occurrence of anti-nuclear antibodies. At a dose of 30 mg/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 20 mg 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 Section 4.6 Adverse reactions.
If overdosage occurs, stop treatment and give symptomatic and supportive care.

4.11 Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antithyroid preparations: sulphur-containing imidazole derivatives.
ATCvet code: QH03BB02.

5.1 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 T_3 and T_4 synthesis.

5.2 Pharmacokinetic particulars

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. Elimination of the drug from cat plasma is rapid with a half-life of 3.5 - 4.0 hours. Peak plasma levels occur approximately 1 - 2 hours after dosing. Cmax is approximately 0.8 µg/ml.
In rats thiamazole has been shown to be poorly bound to plasma protein (5%); 40% was bound to red blood cells. The metabolism of thiamazole in cats has not been investigated, however, in rats thiamazole is rapidly metabolised in the thyroid gland, with 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. The drug residence time in the thyroid gland is assumed to be longer than in the plasma.
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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet core:
Lactose monohydrate
Povidone
Sodium starch glycollate
Magnesium stearate

Coating:
Sucrose
Povidone
Erythrosine
Macrogol
Purified talc
White beeswax
Carnauba wax
Shellac
Titanium dioxide (E171)
Sodium methyl parahydroxybenzoate (E219)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25ºC.
Keep the container tightly closed in order to protect from moisture.
Keep the container in the outer carton.

6.5 Nature and composition of immediate packaging

White polypropylene tub with white low density polyethylene tamper evident lid containing 100 tablets.

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

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

7. MARKETING AUTHORISATION HOLDER

8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION

10. DATE OF REVISION OF THE TEXT

March 2017

Approved: 31 March 2017