Veterinary Medicines Directorate

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Veterinary Medicines Directorate
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NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Thyrasol 5 mg/ml Oral Solution for Cats

Date Created: January 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Thyrasol 5 mg/ml Oral Solution for Cats
Applicant	CP-Pharma Handelsgesellschaft mbH Ostlandring 13 31303 Burgdorf Germany
Active substance	Thiamazole
ATC Vetcode	QH03BB02
Target species	Cats
Indication for use	For the stabilisation of hyperthyroidism in cats prior to surgical thyroidectomy. For the long- term treatment of feline hyperthyroidism.

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Product Information Database of the Veterinary Medicines Directorate.

(www.gov.uk/check-animal-medicine-licensed)

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Generic hybrid application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	19/12/2022

I. SCIENTIFIC OVERVIEW

This was determined a generic hybrid application because the proposed product is in an alternative form to the reference product. The quality / safety / efficacy aspects of this product are identical to Felimazole 5 mg Coated Tablets for Cats. The initial application for Felimazole was assessed before there was a requirement to have a public assessment report, therefore no details in this section are available.

II. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE CONSTITUENTS

II.A. Composition

The product contains thiamazole and the excipients glycerol [E422], povidone K30, sodium benzoate [E211], hypromellose, disodium phosphate dihydrate, sodium dihydrogen phosphate dihydrate [E339], citric acid [E330], sodium cyclamate, sucralose, anise flavour, citric acid solution, sodium hydroxide solution and purified water.

The container/closure system consists of a glass or HDPE bottle closed with a child resistant closure with a syringe in-lay. The particulars of the containers and controls performed are provided and conform to the regulation.

The choice of the formulation and the absence of preservative are justified.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

II.B. Description of the Manufacturing Method

The product is manufactured fully in accordance with the principles of good manufacturing practice from a licensed manufacturing site.
The product is manufactured using conventional manufacturing techniques. However, suitable validation results on two production scale batches per

manufacturing site have been provided. The tests performed during production are described.
A bulk holding time of 28 days has been justified. Process validation data on the product have been presented in accordance with the relevant European guidelines.

II.C. Control of Starting Materials

The active substance is thiamazole, an established active substance described in the European Pharmacopoeia. The active substance is manufactured in accordance with the principles of good manufacturing practice.

The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification have been provided.

A CEP has been provided.

All excipients are described in Ph. Eur. except for sodium hydroxide and anise flavour which comply with in-house monographs.

II.C.4. Substances of Biological Origin

There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

II.D. Control Tests Carried Out at Intermediate Stages of the Manufacturing Process

Not applicable.

II.E. Control Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. The tests in the specification, and their limits, have been justified and are considered appropriate to adequately control the quality of the product. Satisfactory validation data for the analytical methods have been provided. Batch analytical data from the proposed production site<s> have been provided demonstrating compliance with the specification. Control tests on the finished product are those for character, colour, clarity, density, pH, viscosity, identification and assay of thiamazole and sodium benzoate, related substances, filling volume and microbiological purity.

II.F. Stability

Stability data on the active substance have been provided in accordance with applicable European guidelines, demonstrating the stability of the active substance when stored under the approved conditions.

Stability data on the finished product have been provided in accordance with applicable European guidelines. The claimed shelf life can be granted for 24 months.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 24 months.
Shelf life after first opening the immediate packaging: 90 days.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Bioequivalence between the proposed product and the reference product has been established.

Toxicological Studies

Not provided as bioequivalence was demonstrated.

Observations in Humans

Bibliographical information was provided.

User Safety

A user risk assessment was provided in compliance with the relevant guideline.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the product. Therefore the following applicant's user recommendations are appropriate:,

- People with known hypersensitivity (allergy) to thiamazole, or one of the excipients, should avoid contact with the veterinary medicinal product. 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.
- This product may cause skin and/or eye irritation. Avoid skin and eye contact including hand to eye contact.
- In case of accidental skin and/or eye contact, rinse skin and/or eyes immediately with clean running water. If irritation develops, seek medical advice.
- Wash hands with soap and water after administration of the product and handling the vomit of or litter used by treated animals.

- Thiamazole may cause gastrointestinal disturbances, headache, fever, joint pain, pruritus (itching) and pancytopaenia (decrease in blood cells and platelets).
- Avoid oral exposure, including hand-to-mouth contact.
- Do not eat, drink or smoke while handling the product or used litter.
- In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
- Do not leave filled syringes unattended.
- Following administration of the product any residual product remaining on the tip of the dosing syringe should be wiped clean with a tissue. The contaminated tissue should be immediately disposed of.
- The used syringe should be stored with the product in the original carton.
- As thiamazole is a suspected human teratogen, women of child-bearing age must wear non-permeable single-use gloves when administering the product or handling the litter/vomit of treated cats.
- If you are pregnant, think you may be pregnant or are attempting to conceive, you should not administer the product or handle the litter/vomit of treated cats.

Environmental Safety

The Environmental Risk Assessment (ERA) was carried out in accordance with VICH and CVMP guidelines.

Phase I:

The product will only be used in non-food animals and as a result environmental exposure will be low. A Phase II ERA was not required.

IV. CLINICAL DOCUMENTATION

IV.I. Pre-Clinical Studies

Pharmacology

Not required.

Tolerance in the Target Species

Tolerance studies were not required because bioequivalence was established.

IV.II. Clinical Documentation

Laboratory Trials

Not applicable but a bioequivalence study was conducted.

V OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that the benefit/risk profile of the product is favourable.

MODULE 4

POST- AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the Product Information Database of the Veterinary Medicines Directorate website.

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The post-authorisation assessment (PAA) contains information on significant changes which have been made after the original procedure which are important for the quality, safety or efficacy of the product.

The PAA for this product is available on the Product Information Database of the Veterinary Medicines Directorate website.

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