Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (BVL)
Federal Office of Consumer Protection and Food Safety
Mauerstraße 39-42
10117 Berlin
(Germany)

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Felinta 10 mg prolonged-release tablets for cats

Date: 29 June 2022

MODULE 1

PRODUCT SUMMARY

EU Procedure number	DE/V/0341/001/DC
Name, strength and pharmaceutical form	Felinta, 10 mg, prolonged-release tablets
Applicant	Milstein C.V. Patroonsweg 20 E 3892 DB ZEEWOLDE NIEDERLANDE
Active substance(s)	Carbimazole
ATC Vetcode	QH03BB01
Target species	Cats
Indication for use	Treatment of hyperthyroidism and hyperthyroidism-associated clinical signs in cats.

MODULE 2

The Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Application in accordance with Article 13 (1) of Directive 2001/82/EC as amended.
Date of completion of the original Decentralised procedure	29 June 2022
Date product first authorised in the Reference Member State (MRP only)	n.a.
Concerned Member States for original procedure	France

I. SCIENTIFIC OVERVIEW

The product is produced and controlled using validated methods and tests, which ensure the consistency of the product released on the market.
It has been shown that the product can be safely used in the target species; reactions observed are indicated in the SPC.
The product is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

II. QUALITY ASPECTS

A. Qualitative and quantitative particulars

The tablet contains 10 mg carbimazole as active substance and the excipients erythrosine (E127), anhydrous citric acid, microcrystalline cellulose, hypromellose and magnesium stearate.

The container/closure system consists of an Alu - PVC/Alu/OPA thermosealed blister.

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

B. Method of Preparation of the Product

The product is manufactured fully in accordance with the principles of good manufacturing practice at a licensed manufacturing site.

Process validation data on the product have been presented in accordance with the relevant European guidelines.

C. Control of Starting Materials

The active substance is carbimazole, 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.

Scientific data and/or certificates of suitability issued by the EDQM have been provided. There are no substances within the scope of the TSE Guideline present or used in the manufacture of this product.

D. Control on intermediate products

Not applicable.

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 have been provided demonstrating compliance with the specification.

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, demonstrating the stability of the product throughout its shelf life when stored under the approved conditions.

G. Other Information

None.

III. SAFETY AND RESIDUES ASSESSMENT (PHARMACO-TOXICOLOGICAL)

As this is a generic application according to Article 13 (1), and bioequivalence with a reference product has been demonstrated, results of pharmacological and toxicological tests are not required.

Warnings and precautions as listed on the product literature are comparable to those of the reference product. Some of the risk mitigation measures were strengthened during the evaluation process to address the potential hypersensitivity risk associated with the excipients and the risk of intoxication due to accidental ingestion of carbimazole in children. Warnings and precautions are adequate to ensure safety of the product to users and the environment.

III.A Safety Testing

User Safety

The applicant has provided a user safety assessment 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:

Wash hands with soap and water after use and when handling litter used by treated animals.

People with known hypersensitivity to carbimazole or any of the excipients or to antithyroid products 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 advice immediately and show the package leaflet or label to the physician.

Carbimazole is a suspected human teratogen. Pregnant women and women of child-bearing age should wear impermeable gloves when handling the product and urine-, faeces- or vomit-stained materials. Do not break or crush tablets.

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

In children, this product may cause severe side-effects after accidental ingestion. Children should not come into contact with the product. Used blisters should be

inserted back into the outer packaging and stored out of the sight and reach of children.

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 pancytopaenia. Treatment is symptomatic.

Environmental Risk Assessment

A Phase I environmental risk assessment (ERA) was provided according to the CVMP/VICH guidelines.

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because the veterinary medicinal product will only be used in non-food animals.

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13 (1) of Directive 2001/28/EC as amended, and bioequivalence with a reference product has been demonstrated, efficacy studies are not required. The efficacy claims for this product are equivalent to those of the reference product.

IV.A Pre-Clinical Studies

Pharmacology

Since the candidate product has a different formulation than the reference product, the applicant conducted a bioequivalence study which demonstrated that the products are bioequivalent.

Tolerance in the Target Species of Animals

As this is a generic application according to Article 13 (1) of Directive 2001/28/EC as amended, and bioequivalence with a reference product has been demonstrated, results of target animal safety studies are not required. The product literature accurately reflects the type and incidence of adverse effects which might be expected.

IV.B Clinical Studies

Since this is a generic application according to Article 13(1) of Directive 2001/28/EC as amended, and bioequivalence has been demonstrated, no data on clinical efficacy are required.

V . OVERALL CONCLUSION AND BENEFIT– RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

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 Summary of Product Characteristics (SPC), the labelling and package leaflet for this veterinary medicinal product (VMP) is available in the Union Product Database (UPD).

This section 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.

<None>