College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Thyron Vet 200 microgram Tablets for dogs and cats
Thyron Vet 400 microgram Tablets for dogs and cats
Thyron Vet 600 microgram Tablets for dogs and cats
Thyron Vet 800 microgram Tablets for dogs and cats

PRODUCT SUMMARY

EU procedure number	NL/V/0395/001-004
Name, strength and pharmaceutical form	Thyron Vet 200 microgram Tablets for dogs and cats Thyron Vet 400 microgram Tablets for dogs and cats Thyron Vet 600 microgram Tablets for dogs and cats Thyron Vet 800 microgram Tablets for dogs and cats
Applicant	CP Pharma Handelsgesellschaft mbH Ostlandring 13 31303 Burgdorf Germany
Active substance(s)	Levothyroxine (as Levothyroxine sodium)
ATC vetcode	QH03AA01
Target species	Dogs and cats
Indication for use	Treatment of primary and secondary hypothyroidism

PRODUCT INFORMATION

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).

SUMMARY OF ASSESSMENT

Legal basis of original application*	Generic application in accordance with Article 18 of Regulation (EC) 2019/6 as amended (Thyron Vet 200). Hybrid application in accordance with Article 19 of Regulation (EC) 2019/6 as amended (Thyron Vet 400/600/800).
Reference product (RP)	Thyron, 200 mcg tabletten voor honden en katten
Marketing authorisation holder	CP-Pharma Handelsgesell-schaft mbH
MS where the RP is or has been authorised	NL
Marketing authorisation number EU procedure number	REG NL 123519
Date of authorisation	February 2019
Date of completion of the original decentralised procedure	22 November 2023
Date veterinary medicinal product first authorised in the Reference Member State (MRP only)	
Concerned Member States for original procedure	AT, BE, CZ, DE, DK, EE, EL, ES, FI, FR, HU, IE, IT,LT, LV, NO, PL, PT, SE and SK
Concerned Member States for subsequent recognition procedure	-
Withdrawn CMS during original decentralised procedure	-

*Please be aware that certain parts of the dossier may be varied and consequently be subject to protection of technical documentation – for these and other changes of referenceability to parts of the dossier, please see chapter POST-AUTHORISATION PROCEDURES

1. SCIENTIFIC OVERVIEW

The veterinary medicinal product (VMP) is produced and controlled using validated methods and tests, which ensure the consistency of the VMP released on the market.

It has been shown that the VMP can be safely used in the target species; the reactions observed are indicated in the SPC.

The VMP is safe for the user and for the environment, when used as recommended. Suitable warnings and precautions are indicated in the SPC.

The efficacy of the VMP was demonstrated according to the claims made in the SPC.

The overall risk/benefit analysis is in favour of granting a marketing authorisation.

2. QUALITY DOCUMENTATION (physicochemical, biological or microbiological information)

A. Product description

The VMP contain 200 µg, 400 µg, 600 µg and 800 µg Levothyroxine sodium and the following core excipients: Calcium hydrogen phosphate dihydrate, Croscarmellose sodium, Magnesium stearate and Microcrystalline cellulose.
The tablet is cross scored and meant to be broken into equal halves or quarters.

The products are packed in Aluminium-PVC/Alu/oPA blisters, each containing 10 tablets.

The product is an established pharmaceutical form and its development is adequately

described in accordance with the relevant European guidelines.

A bioequivalence study is waived for the generic Levothyroxine sodium 200 µg tablets.

The 400 µg, 600 µg and 800 µg tablets fulfil the requirements of the biowaiver for strengths.

B. Description of the manufacturing method

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

The VMP is manufactured using conventional manufacturing techniques.

The tests performed during production are described

C. Production and control of starting materials

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

A CEP procedure has been employed.

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.

All excipients are in conformity with the Ph.Eur. requirements.
The packaging is conformity with the Ph. Eur. and EU Food Directive.

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

D. Control tests carried out on isolated intermediates during the manufacturing process

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 VMP.

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 tests

Stability data on the finished product have been provided in accordance with applicable European guidelines, demonstrating the stability of the VMP throughout its shelf life when stored under the approved conditions.

According to the stability results provided, the claimed shelf life of 2 years can be granted for the 200 µg / 400 µg / 800 µg tablets and a shelf life of 30 months can be granted for the 600 µg tablets.

G. Other information

Not applicable.

3. SAFETY DOCUMENTATION (safety and residues tests)

Thyron Vet 200: As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, results of safety tests are not required.

Thyron Vet 400/600/800: As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, results of safety tests are not required

The safety aspects of this VMP is/are identical to the reference VMP.

Warnings and precautions as listed on the product literature are the same as those of the reference VMP and supplemented with additional statements, based on increased knowledge and the current state of science. This information is considered adequate to ensure safety of the product to users and the environment.

A. Safety tests

User safety

The applicant has provided a user safety assessment in compliance with the relevant guideline, which shows that that there is a risk after accidental oral ingestion of the product. Also the risk of hypersensitivity reactions has been acknowledged. User safety warnings are in place.

Furthermore, a safety warning for pregnant women is in place.

The user safety warnings are similar to those for recent generic procedures as the reference product does not have safety warnings.

Warnings and precautions as listed on the product literature are adequate to ensure safety to users of the VMP.

Environmental Risk Assessment

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

Phase I:

The environmental risk assessment can stop in Phase I and no Phase II assessment is required because

The VMP will only be used in non-food animals.

4. EFFICACY DOCUMENTATION (preclinical studies and clinical trials)

Thyron Vet 200: As this is a generic application according to Article 18 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, efficacy studies are not required. The efficacy claims for this VMP are equivalent to those of the reference VMP.

Thyron Vet 400/600/800: As this is a hybrid application according to Article 19 of Regulation (EC) 2019/6 and essential similarity to a reference VMP has been demonstrated, efficacy studies are not required.

The efficacy claims for this VMP are equivalent to those of the reference VMP.

5. OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

The data submitted in the dossier demonstrate that when the VMP 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 VMP for humans and the environment is acceptable.

POST-AUTHORISATION PROCEDURES

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the VMP. The current SPC 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 VMP.

None