College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
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The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Catzol 10 mg/ml oral solution for cats

NL/V/0347/001/DC

Created: March 2022

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0347/001/DC
Name, strength and pharmaceutical form	Catzol 10 mg/ml oral solution for cats
Applicant	Vetpharma Animal Health S.L. Carrer De Les Corts 23 08028 Barcelona Spain
Active substance(s)	Itraconazole
ATC Vet code	QJ02AC02
Target species	Cats
Indication for use	Treatment of dermatophytosis caused by *Microsporum canis.*

Catzol 10 mg/ml oral solution for cats	NL/V/0347/001/DC
Vetpharma Animal Health S.L.	DCP
	Publicly available assessment report

MODULE 2

The Summary of Product Characteristics (SPC) for this product is available on the Heads of Veterinary Medicines Agencies website (http://www.HMA.eu).

MODULE 3

PUBLIC ASSESSMENT REPORT

Legal basis of original application	Decentralised application in accordance with Article 13(1) of Directive 2001/82/EC as amended (Generic).
Date of completion of the original decentralised procedure	22 December 2021
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	AT, BE, DE, EL, ES, FR, HU, IT, PL, PT, UK(NI)

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; the slight 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 efficacy of the product was demonstrated according to the claims made in the SPC.
The overall risk/benefit analysis is in favour of granting a marketing authorisation.

The product is authorized in accordance with Article 13(1) of Directive 2001/82/EC as amended. The reference product for this application is Itrafungol 10 mg/ml, orale oplossing (REG NL 10220) marketed in the Netherlands by Eli Lilly Nederland B.V./Elanco Animal Health since 2004, at present MAH Virbac.

II. QUALITY ASPECTS

A. Qualitative and Quantitative particulars of the constituents

Catzol 10 mg/ml Oral Solution is an oral solution containing 10 mg/ml of the active substance Itraconazole. Excipients included are Caramel (E150), Propylene glycol, Sorbitol 70 % non-crystallising solution, Hydroxypropyl-b-cyclodextrin, Concentrated hydrochloric acid, Sodium hydroxide, Sodium saccharin, Cherry flavour and Purified water.

The oral solution is packaged in amber glass bottle (type III) containing 52 ml oral solution, with a shutter and closed with a child resistant polypropylene screw cap with a LDPE insert packaged in a cardboard box with a graduated dosing syringe.

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines. Dosing accuracy of the 3 mL plastic syringe has been demonstrated.

The claimed biowaiver can be granted.

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 pre-approval validation results on three pilot scale batches have been provided.

The tests performed during production are described.

C. Control of Starting Materials

The active substance Itraconazole is an established substance described in the European Pharmacopoeia. The active substance is manufactured at Quimica Sintetica S.A. in accordance with the principles of good manufacturing practice.

A copy of the Certificate of Suitability been provided in the dossier.

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.

Most excipient, in conformity with the Ph.Eur. requirements. For Caramel (E 150) and Cherry flavour in-house specifications are applicable.

None of the starting materials used are affected by the Note for Guidance on TSE/BSE.

D. Control tests carried out at the intermediate stages of the manufacturing process

Not applicable.

E. Tests on the Finished Product

The finished product specification controls the relevant parameters for the pharmaceutical form. All tests in the specification, and their limits, 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 has been provided demonstrating compliance with the specification.

F. Stability tests

The retest period of 5 years for Itraconazole from Quimica Sintetica S.A. when stored under the approved conditions is justified.

Stability data on the finished product have been provided in accordance with applicable the VICH guidelines. According to the stability results provided the claimed shelf life of 6 months stored below 25ºC in a tightly closed container can be granted.

According to the in-use stability results provided the claimed in-use shelf-life of 35 days can be granted.

Catzol 10 mg/ml oral solution for cats	NL/V/0347/001/DC
Vetpharma Animal Health S.L.	DCP
	Publicly available assessment report

G. Other Information

Not applicable.

Catzol 10 mg/ml oral solution for cats	NL/V/0347/001/DC
Vetpharma Animal Health S.L.	DCP
	Publicly available assessment report

III. SAFETY ASSESSMENT (PHARMACO-TOXICOLOGICAL)

III.A

User Safety

The product is authorized in accordance with Article 13(1) of Directive 2001/82/EC as amended. Bioequivalence with the reference product has been demonstrated. The safety claims for this product are equivalent to those of the reference product.

Warning statements and precautions as listed in the product literature are based on those of the reference product 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.

Ecotoxicity

The applicant provided a first phase environmental risk assessment in compliance with the relevant guideline which showed that no further assessment is required.

III.B Residues documentation

Not applicable as the product is intended for cats.

Catzol 10 mg/ml oral solution for cats	NL/V/0347/001/DC
Vetpharma Animal Health S.L.	DCP
	Publicly available assessment report

IV. CLINICAL ASSESSMENT (EFFICACY)

As this is a generic application according to Article 13, 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.

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 current SPC is available on the Heads of Veterinary Medicines Agencies website (www.HMA.eu).

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.