College ter Beoordeling van Geneesmiddelen / Medicines Evaluation Board

Graadt van Roggenweg 500
3531 AH Utrecht
The Netherlands

DECENTRALISED PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Fugasol 10 mg/ml oral solution for cats

NL/V/0374/001/DC

Created:
October 2022

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Cp-Pharma Handelgesellschaft mbH	DCP
	Publicly available assessment report

MODULE 1

PRODUCT SUMMARY

EU Procedure number	NL/V/0374/001/DC
Name, strength and pharmaceutical form	Fugasol 10 mg/ml oral solution for cats
Applicant	Cp-Pharma Handelgesellschaft mbH Ostlandring 13 31303 Burgdorf Germany
Active substance(s)	Itraconazole
ATC Vetcode	QJ02AC02
Target species	Cats
Indication for use	Treatment of dermatophytosis caused by *Microsporum canis.*

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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).

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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	21 September 2022
Date product first authorised in the Reference Member State (MRP only)	N/A
Concerned Member States for original procedure	AT, BE, DE, DK, EE, ES, FI, FR, HU, IE, IT, LT, LV, PL, PT, SE, UK(NI)

Mis en forme : Anglais (États-Unis)

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

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

Mis en forme : Anglais (États-Unis)

The oral solution is packaged in amber glass bottle (type III) or white HDPE screw bottles containing 25, 50 or 100 ml oral solution, with a LDPE syringe in-lay and closed with a child resistant polypropylene screw cap. A graduated dosing syringe is provided.

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.

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The applicant concluded that a biowaiver is not justified. Instead a bioequivalence study was conducted.

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 two small production scale batches have been provided. A post-authorisation commitment has been provided that process validation will be performed on a third production scale batch at the upper batch size range (500 Litre).

The tests performed during production are described.

The maximum holding time of the bulk product has been stated.

C. Control of Starting Materials

The active substance Itraconazole is an established substance described in the European Pharmacopoeia. The active substance is manufactured 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 are in conformity with the Ph.Eur. requirements. For Caramel flavour and Anise 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

Stability data demonstrates stability over 5 years for Itraconazole when stored under the approved conditions. The CEP holder has confirmed a 5 years retest period.

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Stability data on the finished product have been provided in accordance with the applicable VICH guidelines. According to the stability results provided the claimed shelf life of 30 months without specific storage precautions can be granted.

According to the in-use stability results provided the claimed in-use shelf-life of 90 days can be granted. In-use stability results of a batch approaching its end of shelf life is awaited.

G. Other Information

Not applicable.

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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.

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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.

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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.