Veterinary Medicines Directorate

United Kingdom
Veterinary Medicines Directorate
Woodham Lane
New Haw
Addlestone
Surrey KT15 3LS

NATIONAL PROCEDURE

PUBLICLY AVAILABLE ASSESSMENT REPORT FOR A VETERINARY MEDICINAL PRODUCT

Fugasol 10 mg/ml Oral Solution for Cats

Date Created: January 2023

MODULE 1

PRODUCT SUMMARY

Name, strength and pharmaceutical form	Fugasol 10 mg/ml Oral Solution for Cats
Applicant	CP Pharma Handelsgesellschaft mbH Ostlandring 13 31303 Burgdoft Germany
Active substance	Itraconazole
ATC Vetcode	QJ02AC02
Target species	Cats
Indication for use	Treatment of dermatophytosis caused by *Microsporum canis.*

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 application in accordance with Article 13(1) of Directive 2001/82/EC as amended.
Date of conclusion of the procedure	15/12/2022

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Itrafungol 10 mg/ml Oral Solution. The initial application for Itrafungol 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 itraconazole and the excipients hydroxypropylbetadex, propylene glycol, sorbitol 70% non-crystallising solution, saccharin solution, caramel flavour, anise flavour, concentrated hydrochloric acid, sodium hydroxide solution and purified water.

The container/closure system consists of an amber glass or white HDPE bottle and closed with a child resistant closure with PE 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 manufacturing method consists of dissolving, heating, cooling and mixing.

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 itraconazole, 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.

CEP is also provided.

All excipients are described in Ph. Eur. with the exception of the flavourings and sodium hydroxide which are described in house.

II.C.4. Substances of Biological Origin

Scientific data and/or certificates of suitability issued by the EDQM have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products has been satisfactorily demonstrated.

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 sites have been provided demonstrating compliance with the specification. Control tests on the finished product are those for character, colour, clarity, density, pH, identification, assay, 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.

G. Other Information

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

III. SAFETY AND RESIDUES DOCUMENTATION (PHARMACO-TOXICOLOGICAL)

III.A Safety Documentation

Pharmacological Studies

Not required as bioequivalence has been demonstrated with the reference product.

Toxicological Studies

Not required as bioequivalence has been demonstrated with the reference product.

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:,

- In humans, itraconazole has been associated with heart failure due to a negative inotropic effect. Cats suffering from heart diseases should be carefully monitored and the treatment should be withdrawn if the clinical signs deteriorate.
- If a suspected lesion occurs on a human, consult a physician, since *M. canis* dermatophytosis is a zoonotic disease. Therefore, wear latex gloves when clipping hair of infected cats, when handling the animal during treatment or when cleaning the syringe.
- Wash hands and exposed skin after use. In case of accidental contact with eyes, rinse thoroughly with water. In case of pain or irritation, seek medical advice. In case of accidental ingestion, rinse mouth with water.

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 due to the legal basis of the application.

Tolerance in the Target Species

Not required because of the legal basis of the application.

IV.II. Clinical Documentation

Laboratory Trials

Not required as bioequivalence was demonstrated through a conducted study.

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.

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

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.

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