IPAR

Publicly Available Assessment Report for a
Veterinary Medicinal Product

Itrafungol 10 mg/ml Oral Solution

PRODUCT SUMMARY

EU Procedure number	IE/V/0431/001
Name, strength and pharmaceutical form	Itrafungol 10 mg/ml Oral Solution
Active substance(s)	Itraconazole
Applicant	Virbac S.A., (10988), (LOC-100054207), 1ère avenue, 2065 M LID, 06516 Carros, France
Legal basis of application	Full application in accordance with Article 12(3) of Directive 2001/82/EC as amended.
Date of Authorisation	2002
Target species	Cats
Indication for use	Treatment of dermatophytosis caused by *Microsporum canis*.
ATC vet code	QJ02AC02
Concerned Member States	AT, BE, CZ, DE, DK, EL, ES, FI, FR, HU, IT, LU, NL, NO, PT, SE, UK(NI)

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

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

II. QUALITY ASPECTS

A. Qualitative and Quantitative Particulars

The product contains
Itraconazole 10 mg/ml, and the excipients:
Caramel (E150)
Propylene glycol (E1520)
Sorbitol 70 % non-crystallising solution
Hydroxypropyl-b-cyclodextrin
Concentrated hydrochloric acid
Sodium hydroxide
Sodium saccharin

Cherry flavour
Purified water

The container/closure system consists of an amber glass bottle (type III) containing 52 ml oral solution, closed with a child resistant polypropylene screw cap with a LDPE insert packed 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.

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 for the manufacturing process has been presented in accordance with the relevant European guidelines.

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.
The active substance specification is considered adequate to control the quality of the material. Batch analytical data demonstrating compliance with this specification has 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 has been provided.
Batch analytical data from the proposed production site has been provided demonstrating compliance with the specification.

F. Stability

Stability data on the active substance has 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 has 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

Not applicable.

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 benefit/risk profile for the target species is favourable and the quality and safety of the product for humans and the environment is acceptable.

VI. 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 HPRA website.
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.

Changes:
Quality Changes

Summary of change (Application number)	**Approval date**
Submission of a new or updated Ph. Eur. Certificate of suitability or deletion of Ph. Eur. certificate of suitability - IE/V/0431/IA/024/G	14/05/2021
Change in the re-test period/storage period or storage conditions of the active substance where no Ph. Eur. Certificate of Suitability covering the retest period is part of the approved dossier & Change in the manufacturing process of the finished product - UK/V/0203/001/1B/022/G	11/01/2016
Update to a Ph. Eur. certificate of suitablity, addition or replacement of a secondary packaging site of the finished product, addition or replacement of a primary packaging site of the finished product, addition or replacement of a manufacturing site of the finished product, change to the batch release site of the finshed product, change in the test procedure of an excipient - UK/V/0203/1/IB/21/G	07/12/2015
Update to a Ph. Eur. certificate of suitablity - UK/V/0203/001/IA/20	12/05/2015
Change in the name and/or address of the marketing authorisation holder in Portugal only -UK/V/xxxx/IA/044/G	07/11/2013
Change in the name and/or address of the marketing authorisation holder in FR only - UK/V/xxxx/IA/042/G	13/06/2013
Change in the name and/or address of the marketing authorisation holder - UK/V/0157/1/IA/012/G	10/06/2013
Change in test procedure for an excipient - UK/V/0203/IA/16/G	13/11/2012
Submission of an updated Certificate of Suitability - UK/V/0203/001/IA/015	01/01/2011
Change in the batch size within 10-fold of the existing batch size for the finished product - UK/V/0203/001/IA/014	01/01/2011
Change in test procedure of an excipent, change in specification parameter and/or limits of an excipient - UK/V/0203/001/IB/012/G	01/01/2011
Change in the name and/or address of the marketing authorisation holder - UK/V/0203/001/1A/011	20/05/2010
Updated certificate from an already approved manufacturer - UK/V/0203/001/IA/010	19/03/2010
Change in the address of the marketing authorisation holder, in Germany only - UK/V/0203/001/IA/009	23/07/2009
Change in test procedure of the finished product - UK/V/203/001/IB/008	22/12/2008
Addition, replacement or deletion of a measuring or administration device not being an integrated part of the primary packaging. - UK/V/0203/001/1B/006	20/05/2008
Change in shape or dimensions of the container or closure. - UK/V/0203/001/1A/005	24/04/2008
Submission of a new or updated Ph. Eur. Certificate of suitability - UK/V/0203/001/1A/004	26/04/2007
UK/V/0203/001	14/03/2006

Safety/Efficacy Changes

Summary of change (Application number)	**Approval date**
Change(s) to an existing pharmacovigilance system as described in the detailed description of the pharmacovigilance system (DDPS) - IE/V/xxxx/IA/115/G	21/05/2019
Change(s) to an existing pharmacovigilance system as described in the detailed description of the pharmacovigilance system (DDPS) - UK/V/0157/01/IA/15/G	17/04/2014
Change in the Qualified Person for Pharmacovigilance - UK/V/xxxx/001/IA/013/G	27/07/2011