IPAR

Public Assessment Report for a Medicinal Product for Human Use

Scientific discussion

Canesten Athlete's Foot Cream
1% w/w CLOTRIMAZOLE
PA1410/039/013

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 a marketing authorisation for a specific medicinal product for human use. It is made available by the HPRA for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of Directive 2001/83/EC, as amended. 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 medicinal product for marketing in Ireland.

I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the HPRA has granted a marketing authorisation for Canesten Athlete's Foot Cream, from Bayer Limited on 20th February 2015 for the treatment of Tinea pedis.

This application for a marketing authorisation was submitted in accordance with Article 10c of Directive 2001/83/EC and is referred to as an 'informed consent' application. This means that Bayer Limited, the Marketing Authorisation Holder for Canesten Cream 1% (PA 1410/039/002), an authorised medicinal product in Ireland has cross-referred to that dossier in support of the present application. This product has the same qualitative and quantitative composition in terms of active substance and the same pharmaceutical form as Canesten Cream 1%.

The product is not subject to medical prescription, supplied through pharmacies only and promoted to healthcare professionals only.

The Summary of Product Characteristics for (SmPC) for this medicinal product is available on the HPRA's website at http://www.hpra.ie/.

Name of the product	Canesten Athlete's Foot Cream
Name of the active substance (INN)	CLOTRIMAZOLE
Pharmacotherapeutic classification (ATC code)	D01AC01
Pharmaceutical form and strength	1% w/w
Marketing Authorisation Number in Ireland (PA)	PA1410/039/013
Marketing Authorisation Holder	Bayer Limited

II QUALITY ASPECTS

II.1. Introduction

This application is for Canesten Athlete's Foot Cream

II.2 Drug substance

The active substance is Clotrimazole a well/established active substance described in the European Pharmacopoeia, and is manufactured in accordance with the principles of Good Manufacturing Practice (GMP)

The EDQM CEP procedure is used in support of this MAA. The EDQM has granted a Certificate of Suitability for Clotrimazole.

The active substance specification is considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification has been provided.

II.3 Medicinal product

P.1 Composition

Canesten Athlete's Foot Cream is a white oil-in-water type cream.
The cream contains 1% w/w of Clotrimazole (10 mg/g). It also contains the following excipients: Sorbitan stearate, Polysorbate 60, Cetyl palmitate, Cetostearyl alcohol, Octyldodecanol, Benzyl alcohol and Purified water.

P.2 Pharmaceutical Development

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

P.3 Manufacture of the Product

The product is manufactured in accordance with the principles of good manufacturing practice (GMP) at suitably qualified manufacturing sites.

The manufacturing process has been validated according to relevant European/ICH guidelines and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients/*Ancillary Substances*)

All ingredients comply with Ph. Eur. and are adequately controlled by the manufacturer's specifications.

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for semi-solid preparations for cutaneous application and the tests and control limits are considered appropriate for this type of product.

The analytical methods used are described in sufficient detail and are supported by validation data.

Batch analytical data for a number of batches from the proposed production site(s) have been provided, and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

P.6 Packaging material

The product is presented in aluminium tubes with internal lacquer coating and HDPE screw-on caps containing a smooth white oil-in-water type cream supplied in 20g and 50g presentations.
Evidence has been provided that
The materials of the components comply with their respective Ph. Eur. Requirements.
Satisfactory specifications for the container closure systems are provided.

P.7 Stability of the Finished Product

Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines demonstrating the stability of the product for 3 years when stored below 25^{o} C.

II.4 Discussion on Chemical, Pharmaceutical and Biological Aspects

The important quality characteristics of the product are well-defined and controlled. Satisfactory chemical and pharmaceutical documentation has been provided, assuring consistent quality of Canesten Athlete's Foot Cream

III NON-CLINICAL ASPECTS

III.1 Introduction

This active substance is the same as that present in Canesten Cream 1% (PA 1410/039/002) on the Irish market. No new preclinical data have been submitted. As such, no pre-clinical assessment has been made on the application. This is acceptable for this type of application.

III.2 Pharmacology

N/A

III.3 Pharmacokinetics

N/A

III.4 Toxicology

N/A

III.5 Ecotoxicity/environmental risk assessment

N/A

III.6 Discussion on the non-clinical aspects

As this is an informed consent of Canesten Cream 1% (PA 1410/039/002), the assessment of the non-clinical aspects is not required. The non-clinical data related to this product is identical to that for Canesten Cream 1% (PA 1410/039/002).

IV CLINICAL ASPECTS

IV.1 Introduction

Since this application is an informed consent of Canesten Cream 1% (PA 1410/039/002), the efficacy and safety data in support of this product is identical to the up-to-date efficacy and safety data of the Canesten Cream 1% dossier which has been assessed and approved. The pack sizes for this application are 20g and 50g, similar to Canesten Cream 1%.

Clotrimazole is a well known active substance with established efficacy and tolerability.

The indication sought for Canesten Athlete's Foot Cream is for the treatment of Tinea pedis.
The content of the SmPC approved during the national procedure is similar to that accepted for the reference product Canesten Cream 1% (PA 1410/039/002) also marketed by Bayer Limited but without the broader indication for the topical treatment of infections due to superficial dermatophytes, Candida species and other fungi sensitive to the anti-infective: Trichomonas, staphylococcus and Bacteroides.

Like Canesten Cream 1%, the applicant is seeking that Canesten Athlete's Foot Cream is not subject to medical prescription, supplied through pharmacies only and promoted to healthcare professionals only.

IV.2 Pharmacokinetics

The pharmacokinetics for Canesten Athlete's Foot Cream are the same as that for Canesten Cream 1% (PA 1410/039/002).

IV.3 Pharmacodynamics

The pharmacodynamics for Canesten Athlete's Foot Cream are the same as that for Canesten Cream 1% (PA 1410/039/002).

IV.4 Clinical Efficacy

Canesten Athlete's Foot Cream is identical to Canesten Cream 1% (PA 1410/039/002) and has well established efficacy.

IV.5 Clinical Safety

Canesten Athlete's Foot Cream is identical to Canesten Cream 1% (PA 1410/039/002) and has well established safety and tolerability.
The marketing authorisation holder (MAH) submitted a summary of the Pharmacovigilance System, including confirmation of the availability of an EU Qualified Person for Pharmacovigilance (EU-QPPV) and the means for notification of adverse reaction reports in the EU or from a Third Country

Risk Management Plan:

Summary of safety concerns	
Important identified risks	Hypersensitivity Contact dermatitis
Important potential risks	Risk of reproductive toxicity with first trimester use Risk of transfer to neonate during lactation due to secretion into milk Development of resistance Risk of misdiagnosis Risk for environmental exposure
Important missing information	None

No additional risk minimisation measures are proposed or ongoing beyond routine pharmacovigilance.

Periodic Safety Update Report (PSUR)

The next PSUR should be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal.

IV.6 Discussion on the clinical aspects

Since this application is an informed consent of Canesten Cream 1% (PA 1410/039/002), the efficacy and safety data in support of this product is identical to the up-to-date efficacy and safety data of the Canesten Cream 1% dossier which has been assessed and approved.
The pack sizes for this application are 20g and 50g presentations.
The SmPC and PL are acceptable.

V OVERALL CONCLUSIONS

Canesten Athlete's Foot Cream is the same as Canesten Cream 1% (PA 1410/039/002). Canesten Cream 1% (PA 1410/039/002) is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

The HPRA, on the basis of the data submitted considered that Canesten Athlete's Foot Cream was the same as the reference product Canesten Cream 1% (PA 1410/039/002) and therefore granted a marketing authorisation.

VI REVISION DATE

VII UPDATES

This section reflects the significant changes following finalisation of the initial procedure.

Scope	Procedure number	Product Information affected	Date of start of procedure	Date of end of procedure	Approval/ non approval