LÄKEMEDELSVERKET
MEDICAL PRODUCTS AGENCY

Public Assessment Report
Scientific discussion

Terbinafin ABECE

(terbinafine hydrochloride)

Asp no: 2017-0159

This module reflects the scientific discussion for the approval of Terbinafin ABECE. The procedure was finalised on 2017-12-28. For information on changes after this date please refer to the module 'Update'.

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I. INTRODUCTION

Evolan Pharma AB has applied for a marketing authorisation for Terbinafin ABECE 10mg/g Cream. The active substance is terbinafine hydrochloride (svampinfektioner i huden orsakade av dermatofyter som Trichophyton (t ex T. rubrum, T. mentagrophytes, T. verrucosum, T. violaceum), Microsporum canis och Epidermophyton floccosum. Jästinfektioner i huden, främst de orsakade av släktet Candida (t ex Candida albicans).
pityriasis (tinea) versicolor orsakad av Pityrosporum orbiculare (även känd som Malassezia furfur).

For approved indications, see the Summary of Product Characteristics.

The marketing authorisation has been granted pursuant to Article 10(3) of Directive 2001/83/EC.

For recommendations to the marketing authorisation not falling under Article 21a/22 of Directive 2001/83/EC and conditions to the marketing authorisation pursuant to Article 21a or 22 of Directive 2001/83/EC to the marketing authorisation, please see section VI.

II. QUALITY ASPECTS

II.1 Drug Substance

The structure of the drug substance has been adequately proven and its physico-chemical properties are sufficiently described.

The manufacture of the drug substance has been adequately described and satisfactory specifications have been provided for starting materials, reagents and solvents.

The drug substance specification includes relevant tests and the limits for impurities and degradation products have been justified. The analytical methods applied are suitably described and validated.

Stability studies confirm the retest period.

II.2 Medicinal Product

The medicinal product is formulated using excipients listed in section 6.1 in the Summary of Product Characteristics.

The manufacturing process has been sufficiently described and critical steps identified.

The tests and limits in the specification are considered appropriate to control the quality of the finished product in relation to its intended purpose.

Stability studies have been performed and data presented support the shelf life and special precautions for storage claimed in the Summary of Product Characteristics, sections 6.3 and 6.4.

III. NON-CLINICAL ASPECTS

Pharmacodynamic, pharmacokinetic and toxicological properties of terbinafine are well known. As terbinafine is a widely used, well-known active substance, no further studies are required and the applicant provides none. Overview based on literature review is, thus, appropriate.

III.1 Ecotoxicity/environmental risk assessment

Since Terbinafin ABECE is intended for generic substitution, this will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.

There are no objections to approval of Terbinafin ABECE from a non-clinical point of view.

IV. CLINICAL ASPECTS

IV.1 Pharmacokinetics

No pharmacokinetic studies have been performed for this product. Terbinafin ABECE is a product for topical application on the skin. After topical application of terbinafine in humans less than 5% of the dose is absorbed. Hence, conventional pharmacokinetic bioequivalence studies are not relevant due to low systemic exposure to terbinafine. The absence of pharmacokinetic studies is acceptable.

IV.2 Pharmacodynamics/Clinical efficacy/Clinical safety

The performed therapeutic equivalence study showed similar efficacy and safety profiles as the comparator Lamisil® cream.

IV.3 Risk Management Plans

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Terbinafin ABECE.

Safety specification

Summary table of safety concerns as approved in RMP

Important identified risks	Allergic recations
Important potential risks	Use during pregnancy Use during pregnancy
Missing information	Use in paediatric pupulation

Pharmacovigilance Plan

Routine pharmacovigilance is suggested and no additional pharmacovigilance activities are proposed by the applicant, which is endorsed.

Risk minimisation measures

Routine risk minimisation is suggested and no additional risk minimisation activities are proposed by the applicant, which is endorsed.

Summary of the RMP

The RMP is approved.

V. USER CONSULTATION

A user consultation with target patient groups on the package information leaflet (PIL) has been performed on the basis of a bridging report making reference to Terbinafin Apofri 10 mg/g cream, Dnr. 111:2011/38132. The bridging report submitted by the applicant has been found acceptable.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

The quality of the generic product, Terbinafin ABECE, is found adequate. There are no objections to approval of Terbinafin ABECE, from a non-clinical and clinical point of view. The product information is acceptable.

The application is therefore recommended for approval.

List of recommendations not falling under Article 21a/22 of Directive 2001/83/EC in case of a positive benefit risk assessment

N/A

List of conditions pursuant to Article 21a or 22 of Directive 2001/83/EC

N/A

VII. APPROVAL

Terbinafin ABECE, 10mg/g, cream was approved in the national procedure on 2017-12-28.

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Public Assessment Report – Update

Procedure number*	Scope	Product Information affected	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse

*Only procedure qualifier, chronological number and grouping qualifier (when applicable)

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