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IRISH MEDICINES BOARD

PUBLIC ASSESSMENT REPORT FOR A MEDICINAL PRODUCT FOR HUMAN USE

SCIENTIFIC DISCUSSION

CALDESENE ADULT 10% W/W MEDICATED POWDER
CALCIUM UNDECYLENATE
PA0126/247/001

The Public Assessment Report reflects the scientific conclusion reached by the Irish Medicines Board (IMB) 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 IMB 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 IMB 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 IMB has granted a marketing authorisation for Caldesene Adult 10% w/w medicated powder from Clonmel Healthcare on 14th March 2014 for protection against skin irritation and chaffing, especially in delicate skin folds.

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 the Marketing Authorisation Holder for 'Caldesene 10% w/w medicated powder', an authorised medicinal product in Europe, has permitted the applicant to refer to their dossier to obtain an authorisation for 'Caldesene Adult 10% w/w medicated powder'. 'Caldesene Adult 10% w/w medicated powder' has the same qualitative and quantitative composition in terms of actives substances and the same pharmaceutical form as 'Caldesene 10% w/w medicated powder '.

Caldesene Adult 10% w/w medicated powder is not subject to medical prescription and may be supplied through non-pharmacy outlets and pharmacies.

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

Name of the product	Caldesene Adult 10% w/w medicated powder
Name(s) of the active substance(s) (INN)	CALCIUM UNDECYLENATE
Pharmacotherapeutic classification (ATC code)	D01AE
Pharmaceutical form and strength(s)	10% w/w Medicated Powder
Marketing Authorisation Number(s) in Ireland (PA)	PA0126/247/001
Marketing Authorisation Holder	Clonmel Healthcare Ltd

II QUALITY ASPECTS

This application is for 'Caldesene Adult 10% w/w medicated powder'.

'Caldesene Adult 10% w/w medicated powder' is the same as 'Caldesene 10% w/w medicated powder'. 'Caldesene 10% w/w medicated powder' is a well-known medicinal product with a proven chemical-pharmaceutical quality.
The IMB, on the basis of the data submitted considered that 'Caldesene Adult 10% w/w medicated powder' was the same as the reference product and therefore granted a marketing authorisation.

III NON-CLINICAL ASPECTS

This active substance is the same as that present in Caldesene 10% w/w medicated powder on the European 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.

IV CLINICAL ASPECTS

IV.1 Introduction

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

This medicinal product is the same as Caldesene 10% w/w medicated powder on the European market.

The content of the SmPC approved during the national procedure is in accordance with that accepted for the reference product Caldesene 10% w/w medicated powder marketed by Clonmel Helathcare Limited.

IV.2 Pharmacokinetics

As this is an informed consent application no bioequivalence study is required.

IV.3 Pharmacodynamics

Calcium undecylenate has antibacterial and antifungal properties.

IV.4 Clinical Efficacy

Calcium undecylenate is a well known active substance with established efficacy. No new studies have been submitted and none are required for an application of this type.

IV.5 Clinical Safety

The safety profile for calcium undecylenate is well known.

The marketing authorisation holder (MAH) submitted a summary describing the Pharmacovigilance System, including information on 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.

A Risk Management Plan has been submitted. Clonmel Helathcare Limited already has a marketing authorisation for this substance and routine pharmacovigilance is already ongoing. All known and identified risks as well as interactions are sufficiently covered in the respective sections of the Summary of Product Characteristics.

The marketing authorisation holder shall submit periodic safety update reports for this product in accordance with the requirements set out in the list of Union reference dates (EURD list) for undecylenic acid provided under Article 107c (7) of Directive 2001/83/EC and published on the European medicines web-portal. The submission cycle is 13 years and the first data lock point (DLP) is 01/01/2025.

IV.6 Discussion on the clinical aspects

The application was submitted as an informed consent application according to Article 10(c) of Directive 2001/83/EC.

No new clinical data have been supplied with this application and none are required for an application of this type.

V OVERALL CONCLUSIONS

Caldesene Adult 10% w/w medicated powder is the same as Caldesene 10% w/w medicated powder. Caldesene 10% w/w medicated powder is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

The SmPC is consistent with that of the reference product.

The MAH has provided written confirmation that systems and services are in place to ensure compliance with their pharmacovigilance obligations.

The IMB, on the basis of the data submitted considered that Caldesene Adult 10% w/w medicated powder was the same as the reference product and therefore granted a marketing authorisation.