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IRISH MEDICINES BOARD

PUBLIC ASSESSMENT REPORT FOR A MEDICINAL PRODUCT FOR HUMAN USE

Scientific discussion

Unicough Chesty 250 mg/5 ml Oral Solution

CARBOCISTEINE

PA 281/142/1

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 Unicough Chesty 250 mg/5 ml Oral Solution, from Pinewood Laboratories Ltd on 19th August 2012 for adjunctive therapy in lower respiratory tract disorders characterised by excessive viscous mucous.

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 Viscolex Syrup 250 mg/5 ml Oral Solution, an authorised medicinal product in Europe, has permitted the applicant to refer to their dossier to obtain an authorisation for carbocysteine. Unicough Chesty 250 mg/5 ml Oral Solution has the same qualitative and quantitative composition in terms of actives substances and the same pharmaceutical form as Viscolex Syrup 250 mg/5 ml Oral Solution.

This product is authorised for retail sale through pharmacies, and can be advertised to healthcare professionals only.

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

Name of the product	Unicough Chesty 250 mg/5 ml Oral Solution
Name(s) of the active substance(s) (INN)	CARBOCISTEINE
Pharmacotherapeutic classification (ATC code)	R05CB03
Pharmaceutical form and strength(s)	250 mg/5 ml
Marketing Authorisation Number(s) in Ireland (PA)	PA 281/142/1
Marketing Authorisation Holder	Pinewood Laboratories Ltd T/a Pinewood Healthcare

II QUALITY ASPECTS

II.1. Introduction

This application is for Unicough Chesty 250 mg/5 ml Oral Solution.

II.2 Drug substance

The active substance is carbocisteine, an established active substance described in the European Pharmacopoeia, and is manufactured in accordance with the principles of Good Manufacturing Practice (GMP)

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

Unicough Chesty is a clear, yellow, oral solution with an odour and flavour of orange.

Each 5 ml of the oral solution contains 250 mg of carbocisteine.

The other constituents of the product are: sucrose, sunset yellow (E110), sodium methyl parahydroxybenzoate (E219), sodium ethyl parahydroxybenzoate (E215), sodium propyl parahydroxybenzoate (E217), disodium edetate, sodium hydroxide, glycerol (E422), orange flavour (contains ethanol), citric acid monohydrate, 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. or 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 ‘Liquid preparations for oral use’, 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 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 filled into amber glass bottles closed with aluminium roll-on pilfer-proof screw caps, containing 100 ml

or 250 ml of solution. Each bottle is packaged in an outer carton and is supplied with a polypropylene measuring spoon.

Evidence has been provided that the bottles meet the requirements of the Ph. Eur. for Type III glass (‘Glass containers for pharmaceutical use’).

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 at a temperature not exceeding 25 °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 Unicough Chesty 250 mg/5 ml Oral Solution

III NON-CLINICAL ASPECTS

This active substance is the same as that present in Viscolex Syrup 250 mg / 5 ml Oral Solution on the European market. No new pre-clinical 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

Carbocysteine is a well known active substance with established efficacy and tolerability. This medicinal product is the same as Viscolex Syrup on the European market. As this is an “informed consent” procedure, no new clinical information has been supplied, and this is acceptable for this type of procedure.

The content of the SPC approved during the national procedure is in accordance with that accepted for the reference product Viscolex Syrup marketed by Pinewood Laboratories.

The Marketing Authorisation Holder submitted a set of documents 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.

V OVERALL CONCLUSIONS

Benefit/Risk Assessment and Recommendation

Unicough Chesty 250mg/5ml Oral Solution is the same as Viscolex Syrup, which is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

The IMB, on the basis of the data submitted, considered that Unicough Chesty was the same as the reference product and therefore granted a marketing authorisation.