IPAR

IRISH MEDICINES BOARD

PUBLIC ASSESSMENT REPORT FOR A MEDICINAL PRODUCT FOR HUMAN USE

Scientific discussion

Strepsils Antiseptic Lozenges
2, 4-Dichlorobenzyl alcohol 1.2 mg,
Amylmetacresol 0.6mg

Strepsils Throat Lozenges
2, 4-Dichlorobenzyl alcohol 1.2 mg,
Amylmetacresol 0.6mg

(2, 4-Dichlorobenzyl alcohol 1.2 mg, Amylmetacresol 0.6mg)

PA0979/057/001
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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

"For mouth and throat infections"

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 'Strepsils Original Lozenges' (PA 979/38/1) , an authorised medicinal product in Europe, has permitted the applicant to refer to their dossier to obtain an authorisation for this product which contains the same active ingredients (namely 2, 4-Dichlorobenzyl alcohol 1.2 mg and Amylmetacresol 0.6). 'Strepsils Antiseptic Lozenges' and 'Strepsils Throat Lozenges' have the same qualitative and quantitative composition in terms of actives substances and the same pharmaceutical form as 'Strepsils Original Lozenges'.

These products are not be subject to prescription and are licensed for general sale. They can be promoted directly to the public.

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	Strepsils Antiseptic Lozenges Strepsils Throat Lozenges
Name(s) of the active substance(s) (INN)	2, 4-Dichlorobenzyl alcohol 1.2 mg Amylmetacresol 0.6mg
Pharmacotherapeutic classification (ATC code)	Not specified in SPC
Pharmaceutical form and strength(s)	Lozenges
Marketing Authorisation Number(s) in Ireland (PA)	PA 979/57/1 PA 979/58/1
Marketing Authorisation Holder	Reckitt Benckiser

II QUALITY ASPECTS

II.1. Introduction

This application is for two duplicate licences which are for identical products to an already licenced product. As all Quality aspects are identical to those of the authorised Strepsils Original product Module 3 data has not been submitted and therefore not assessed.
The names of the products are:

Strepsils Throat Lozenges
2, 4-Dichlorobenzyl alcohol 1.2 mg,
Amylmetacresol 0.6mg

And

Strepsils Antiseptic Lozenges
2, 4-Dichlorobenzyl alcohol 1.2 mg,
Amylmetacresol 0.6mg

II.2 Drug substance

The two active substances are Amylmetacresol B.P. and 2, 4-dichlorobenzyl alcohol, both are established active substances.
Amylmetacresol is described in British Pharmacopoeia, while 2, 4-dichlorobenzyl alcohol is non-pharmacopoeial and both are manufactured in accordance with the principles of Good Manufacturing Practice (GMP).

II.3 Medicinal product

P.1 Composition
A circular, biplanar red lozenge with an aniseed odour, embossed on both sides with Strepsils brand icon.

Composition
Active substances
Amylmetacresol BP
2, 4-Dichlorobenzyl alcohol

Excipients
Star Anise Oil Ph. Eur.
Peppermint Oil Ph. Eur.
Levomenthol Ph. Eur.
Tartaric Acid Ph. Eur.
Ponceau 4R (E 124)
Carmoisine (E122)
Glucose Ph. Eur.
Sucrose Ph. Eur.

P.2 Pharmaceutical Development

The product is an established pharmaceutical.

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.

P.4 Control of Other Substances (Excipients)

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 identical to that for 'Strepsils Original Lozenges'.
Which is based on the pharmacopoeial monograph for solid dosage forms, lozenges, and the tests and control limits are considered appropriate for this type of product.

Using the information previously supplied for the above product, analytical methods used are considered described in sufficient detail and are supported by validation data and batch analytical data for a number of batches from the proposed production site. This demonstrates the manufacturer's ability to produce batches of finished product of consistent quality.

P.6 Packaging material

As for the reference product, the product is presented as a blister push-through tray of PVC/PVDC laminate heat-sealed to aluminium foil packed in a cardboard carton with tamper-evident seal.

P.7 Stability of the Finished Product

Using the reference product the products are considered stable for 3 years when stored at a temperature not above 25°C.

II.4 Discussion on Chemical, Pharmaceutical and Biological Aspects

The important quality characteristics of the product are as those accepted for the reference product marketed by Reckitt Benckhiser, based on this the consistent quality of the following are assured:

Strepsils Throat Lozenges
2, 4-Dichlorobenzyl alcohol 1.2 mg,
Amylmetacresol 0.6mg

And

Strepsils Antiseptic Lozenges
2, 4-Dichlorobenzyl alcohol 1.2 mg,
Amylmetacresol 0.6mg

III NON-CLINICAL ASPECTS

III.1 Introduction

These active substances are the same as those present in ‘Strepsils Original Lozenges’on the European market. No new preclinical data have been submitted. As such, no pre-clinical assessment has been made on the application.

IV CLINICAL ASPECTS

IV.1 Introduction

2, 4-Dichlorobenzyl alcohol 1.2 mg/Amylmetacresol 0.6 are well known active substances with established efficacy and tolerability. These medicinal products are the same as ‘Strepsils Original Lozenges’on the European market

The content of the SPCs approved during this national procedure is in accordance with that accepted for the reference product marketed by Reckitt Benckhiser.

V OVERALL CONCLUSIONS

BENEFIT/RISK ASSESSMENT AND REOMMENDATION

‘Strepsils Antiseptic Lozenges’ and ‘Strepsils Throat Lozenges’ are the same as ‘Strepsils Original Lozenges’ which is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established efficacy and safety profile.

The IMB, on the basis of the data submitted considered that ‘Strepsils Antiseptic Lozenges’ and ‘Strepsils Throat Lozenges’ were the same as the reference product and therefore granted a marketing authorisation.

VI REVISION DATE

July 2009