# IPAR


## PUBLIC ASSESSMENT REPORT FOR A MEDICINAL PRODUCT FOR HUMAN USE

Scientific discussion

Strepsils Sugar Free Lozenges
Amylmetacresol 600 micrograms
2,4-Dichlorobenzyl alcohol 1.2 mg
PA 979/62/1

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 Strepsils Sugar Free Lozenges, Amylmetacresol 600 micrograms, 2,4−Dichlorobenzyl alcohol 1.2 mg, from Reckitt Benckiser Ireland Ltd. on 3rd June 2011 for the symptomatic relief of mouth and throat infections including sore throat.

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 Strawberry Sugar Free Lozenges, an authorised medicinal product in Europe, has permitted the applicant to refer to their dossier to obtain an authorisation for Strepsils Sugar Free Lozenges, Amylmetacresol 600 micrograms, 2,4−Dichlorobenzyl alcohol 1.2 mg, which have the same qualitative and quantitative composition in terms of active substances and the same pharmaceutical form as Strepsils Strawberry Sugar Free Lozenges.

The product is not subject to medical prescription, and is licensed for general sale.

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

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|---|---|
| Name of the product | Strepsils Sugar Free Lozenges |
| Names of the active substances (INN) | AMYLMETACRESOL, 2,4−DICHLOROBENZYL ALCOHOL |
| Pharmacotherapeutic classification (ATC code) | R02AA03 (antiseptics) |
| Pharmaceutical form and strength(s) | 0.6/1.2 milligram Lozenges |
| Marketing Authorisation Number(s) in Ireland (PA) | PA 979/62/1 |
| Marketing Authorisation Holder | Reckitt Benckiser Ireland Ltd |

# II QUALITY ASPECTS

## II.1. Introduction

This application is for Strepsils Sugar Free Lozenges, Amylmetacresol 600 micrograms, 2,4-Dichlorobenzyl alcohol 1.2 mg.

## II.2 Drug substance

The active substances are amylmetacresol and 2,4-dichlorobenzyl alcohol, established active substances which are manufactured in accordance with the principles of Good Manufacturing Practice (GMP)

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

## II.3 Medicinal product

P.1 Composition

The product is a pink, circular lozenge with a characteristic strawberry taste, embossed on both sides with Strepsils brand icon.

Each lozenge contains 600 µg of amylmetacresol and 1.2 mg of 2,4-dichlorobenzyl alcohol.

The formulation also contains the following ingredients: strawberry flavor, Ponceau 4R (E124), sodium saccharin, tartaric acid, isomalt and maltitol syrup.

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 is considered to be sufficiently validated.

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

All ingredients comply with Ph. Eur. monographs 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 oromucosal preparations, 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 presented in an alumininium/PVC-PVdC blister within an outer carton.

Evidence has been provided that the blister complies with EU legislation for plastic materials intended for use with foodstuffs.

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 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 Strepsils Sugar Free Lozenges, amylmetacresol 600 micrograms, 2,4-Dichlorobenzyl alcohol 1.2 mg.

## III NON-CLINICAL ASPECTS

This active substance is the same as that present in Strepsils Strawberry Sugar free lozenges 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

*Other areas to address in generic applications:*
- *Risk Management Plan (usual pharmacovigilance requirements and/or additional requirements)*
- *The proposed schedule for submission of PSURs should be addressed.*

Amylmetacresol and 2,4-Dichlorobenzyl Alcohol are well known active substances with established efficacy and tolerability. This medicinal product is the same as Strepsils Strawberry Sugar free lozenges on the European market.

The content of the SPC approved during the national procedure is in accordance with that accepted for the reference product.

## IV.2 Pharmacology

Strepsils lozenges have disinfectant and antiseptic properties.

## IV.4 Clinical Efficacy

Clinical efficacy has been assessed during the original application, and will not be reassessed here.

## IV.5 Clinical Safety

The clinical ssafety profile has been established for the reference product. As the active ingredients in this application are identical to the originator product, a similar sagety profile is assumed for this product. Further details regarding the post-marketing safety reporting requirements an be found below.

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.

## IV.6 Discussion on the clinical aspects

As this is an application under Article 10c of the Directive (“informed consent”), no new clinical information has been provided as part of this application. This is acceptable. The clinical efficacy and safety of the active ingredients are well-established

# V OVERALL CONCLUSIONS

Strepsils Sugar free lozenges are the same as Strepsils Strawberry Sugar free lozenges Strepsils Strawberry Sugar free lozenges are a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile.

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 Strepsils Sugar free lozenges were the same as the reference product and therefore granted a marketing authorisation.