

**IPAR**



IRISH MEDICINES BOARD

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

Scientific discussion

Strepsils with Vitamin C Lozenges  
AMYLMETACRESOL 0.6mg  
2,4-D ICHLOROBENZYL ALCOHOL 1.2mg  
VITAMIN C 100mg  
PA0979/039/002

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 with Vitamin C Lozenges, Amylmetacresol 0.6mg, 2,4-Dichlorobenzylalcohol 1.2mg, Vitamin C 100mg, from Reckitt Benckiser Ireland Ltd. on 19<sup>th</sup> July 2013 for the symptomatic relief of mouth and throat infection.

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 Orange with Vitamin C lozenges, an authorised medicinal product in Europe, has permitted the applicant to refer to their dossier to obtain an authorisation for this product. Strepsils with Vitamin C Lozenges, Amylmetacresol 0.6mg, 2,4-Dichlorobenzylalcohol 1.2mg, Vitamin C 100mg has the same qualitative and quantitative composition in terms of actives substances and the same pharmaceutical form as Strepsils Orange with Vitamin C Lozenges, Amylmetacresol 0.6mg, 2,4-Dichlorobenzylalcohol 1.2mg, Vitamin C 100mg. The products are not subject to medical prescription can be promoted to the general publicand are for general sale.

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

Name of the product	Strepsils with Vitamin C Lozenges
Name(s) of the active substance(s) (INN)	Amylmetacresol 2,4-Dichlorobenzyl alcohol Vitamin C (as Ascorbic Acid and Sodium Ascorbate)
Pharmacotherapeutic classification (ATC code)	R02AA03
Pharmaceutical form and strength(s)	Lozenge, 100mg
Marketing Authorisation Number(s) in Ireland (PA)	PA0979/039/002
Marketing Authorisation Holder	Reckitt Benckiser Ireland Ltd

II QUALITY ASPECTS

II.1. Introduction

This application is for Strepsils with Vitamin C Lozenges, Amylmetacresol 0.6mg, 2,4-Dichlorobenzylalcohol 1.2mg, Vitamin C 100mg.

II.2 Drug substance

The active substances are Amylmetacresol, 2,4-Dichlorobenzylalcohol and Vitamin C (as Ascorbic acid and Sodium Ascorbate), established active substances described in the European Pharmacopoeia and/or British Pharmacopoeia, and are manufactured in accordance with the principles of Good Manufacturing Practice (GMP)

The active substance specification for each active substance 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

Each lozenge is circular and is orange flavoured and coloured. Embossed on both sides is the strepsils brand icon.

Each lozenge contains levomenthol, tartaric acid, flavour Givaudan Blood Orange 78300-34, sunset yellow FCF (E110), ponceau 4R (E124), propylene glycol, liquid glucose and liquid sucrose

#### 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)

All ingredients comply with Ph. Eur. or in-house standards and are therefore adequately controlled by the agreed specifications.

#### P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for lozenges 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(s) 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 as two blister trays, each containing 12 lozenges.

Evidence has been provided that the blisters comply with Ph. Eur. and EU legislation for use with foodstuffs requirements, where applicable.

#### 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 below 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 with Vitamin C Lozenges, Amylmetacresol 0.6mg, 2,4-Dichlorobenzylalcohol 1.2mg, Vitamin C 100mg.

## III NON-CLINICAL ASPECTS

### III.1 Introduction

This active substance is the same as that present in Strepsils Orange with Vitamin C 100mg 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

2, 4-Dichlorobenzyl alcohol and amylmetacresol are well known active substances with established efficacy and tolerability. This medicinal product is the same as Strepsils Orange with Vitamin C 100mg 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 Strepsils Orange with Vitamin C 100mg Lozenges marketed by Reckitt Benckiser Ltd.

### IV.2 Pharmacological profile

2,4-Dichlorobenzyl alcohol and amylmetacresol have antiseptic properties. Ascorbic acid and sodium ascorbate provide a source of Vitamin C, which may be beneficial during infection when Vitamin C levels are believed to fall.

No additional risk minimisation measures are required for this product outside those required for routine pharmacovigilance.

The schedule for Periodic Safety Update Reports (PSUR) submission is identical to that of the reference product.

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

The safety and efficacy of the active ingredients are well established. As this is an application under Article 10c of Directive 2001/83/EC ("informed consent") no additional evidence to support the safety and efficacy is required.

## V OVERALL CONCLUSIONS

### Benefit/Risk Assessment and Recommendations

The overall assessment outcome of Strepsils with Vitamin C Lozenges, Amylmetacresol 0.6mg, 2,4-Dichlorobenzylalcohol 1.2mg, Vitamin C 100mg is positive.

Strepsils with Vitamin C 100mg Lozenges are the same as Strepsils Orange with Vitamin C 100mg Lozenges. It 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 Strepsils with Vitamin C 100mg Lozenges marketed by Reckitt Benckiser Ltd was the same as the reference product and therefore granted a marketing authorisation.