

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Strepsils Strawberry Sugar Free Lozenges Amylmetacresol 600 micrograms 2, 4-Dichlorobenzyl Alcohol 1.2 mg

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains amylmetacresol 600 micrograms and 2, 4-Dichlorobenzyl alcohol 1.2 mg.

Excipients with known effects: Propylene Glycol 7.30 mg/lozenge.

Isomalt (E 953) 1.83 g (1830 mg)/lozenge.

Maltitol liquid (E 965) 0.458 g (458 mg)/lozenge.

Benzyl Alcohol (present in Strawberry flavour) 0.0028 mg/lozenge.

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Lozenge

Pink, circular lozenge with a characteristic strawberry taste, embossed on both sides with strepsils brand icon.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Strepsils Sugar Free are indicated for the symptomatic relief of mouth and throat infections including sore throat.

### 4.2 Posology and method of administration

#### **Posology**

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. It is recommended that the product should be used for a maximum of 3 days.

#### **Adults:**

One lozenge every 2-3 hours. Do not take more than 12 lozenges in 24 hours.

#### **Paediatric population:**

**Children over 6 years of age:** As above for adults.

#### **Children under 6 years of age:**

Not suitable for children under 6 years (see section 4.4)

#### **Elderly:**

There is no need for dosage reduction in the elderly.

#### **Method of administration**

For oromucosal administration. To be dissolved slowly in the mouth.

### 4.3 Contraindications

Strepsils Strawberry Sugar Free Lozenges are contraindicated in persons who have previously shown hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

### 4.4 Special warnings and precautions for use

This product is not recommended for young children due to a risk of choking.

Consult your doctor if symptoms persist or if anything unusual happens.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'.

This medicine contains 7.30 mg propylene glycol (present in strawberry flavour) in each lozenge.

This medicine also contains 1.83 g isomalt and 0.458 g maltitol liquid. Patients with rare hereditary problems of fructose intolerance should not take this medicine. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May have a mild laxative effect. Calorific value 2.3 kcal/g.

This medicine contains 0.0028 mg benzyl alcohol in each lozenge which may cause allergic reactions.

#### 4.5 Interaction with other medicinal products and other forms of interactions

Not applicable.

#### 4.6 Fertility, pregnancy and lactation

##### Pregnancy

There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of amylmetacresol and 2,4-dichlorobenzyl alcohol in pregnant women. As a precautionary measure, it is preferable to avoid the use of Strepsils during pregnancy.

##### Breast-feeding

There is insufficient information on the excretion of amylmetacresol or 2,4-dichlorobenzyl alcoholmetabolites in human milk. A risk to the newborns/infants cannot be excluded.

##### Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

#### 4.7 Effects on ability to drive and use machines

No adverse effects are known.

#### 4.8 Undesirable effects

The list of the following adverse effects relates to those experienced with 2,4- dichlorobenzyl alcohol and amylmetacresol at OTC doses, in short term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

Adverse events which have been associated with 2,4-dichlorobenzyl alcohol and amylmetacresol are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common ( $\geq 1/10$ ); Common ( $\geq 1/100$  and  $< 1/10$ ); Uncommon ( $\geq 1/1000$  and  $< 1/100$ ); Rare ( $\geq 1/10,000$  and  $< 1/1000$ ); Very rare ( $< 1/10,000$ ); Not known (cannot be estimated from the available data). Within each frequency grouping, adverse events are presented in order of decreasing seriousness.

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Not known	Hypersensitivity <sup>1</sup>
Gastrointestinal Disorders	Not known	Abdominal pain, nausea, oral discomfort <sup>2</sup>
Skin and Subcutaneous Tissue Disorders	Not known	Rash

##### Description of Selected Adverse Reactions

<sup>1</sup> Hypersensitivity reactions may present in the form of rash, angioedema, urticaria, bronchospasms and hypotension with syncope.

<sup>2</sup> Oral discomfort may present in the form of throat irritation, oral paraesthesia, oedema of the mouth and glossodynia.

##### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued

monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: [www.hpra.ie](http://www.hpra.ie); e-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie).

## 4.9 Overdose

### Symptoms:

In view of the nature and presentation of Strepsils Sugar Free Lozenges, accidental or deliberate overdosage is highly unlikely.

Overdosage should not present a problem other than gastrointestinal discomfort.

### Management:

Treatment should be symptomatic.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

**Pharmacotherapeutic group:** Throat Preparations; Antiseptics;

**ATC Code:** R02AA03 Dichlorobenzyl alcohol

#### Mechanism of Action

2, 4-Dichlorobenzyl alcohol and amylmetacresol are antiseptics and possess antibacterial, antifungal and antiviral properties. Both AMC and DCBA also reversibly block depolarisation-induced ion channels in a similar way to local anaesthetics. When the two active agents are combined, a synergistic antibacterial action is observed leading to the reduced combined dose used in Strepsils lozenges.

#### Clinical efficacy and safety

Evidence of an analgesic effect for Strepsils in reducing throat soreness, providing pain relief and relief from difficulty in swallowing has been demonstrated to clinical studies with an onset in 5 minutes which lasts for up to 2 hours. Significantly more relief than nonmedical lozenge was also demonstrated for up to 3 days treatment.

Strepsils lozenge have also been shown to significantly decrease postoperative throat soreness and hoarseness 20 minutes and 24 hours after intubation.

A study in children (6-16 years) with acute and recurring chronic sore throat demonstrates a reduction in subjective and objective signs of sore throat over 3 days.

Strepsils Strawberry Sugar Free lozenge base has a demulcent action providing throat soothing.

### 5.2 Pharmacokinetic properties

No data available.

### 5.3 Preclinical safety data

Not applicable.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Strawberry Flavour 052312B (contains benzylalcohol)

Pink Antho (E163)

Sodium Saccharin (E954)

Tartaric Acid

Isomalt (E953)

Maltitol Syrup (E965)

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

2 years.

## **6.4 Special precautions for storage**

Do not store above 25°C

## **6.5 Nature and contents of container**

The lozenges are packed in blisters made up of white (opaque) 250 micron Polyvinyl Chloride (PVC), coated with 90 g/m<sup>2</sup> Polyvinylidene Chloride (PVDC).

The blisters are heat sealed to 20 microns Aluminium lidding material coated with 7 g/m<sup>2</sup> of heat sealing lacquer.

Each blister contains 6, 8, 10, 12, 16, 20 or 24 lozenges. Two trays are packed in a carton or for two lozenge sample two blisters are attached to a stencilled card.

Not all pack sizes may be marketed.

## **6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product**

No special requirements.

## **7 MARKETING AUTHORISATION HOLDER**

Reckitt Benckiser Ireland Ltd  
7 Riverwalk  
Citywest Business Campus  
Dublin 24  
Ireland

## **8 MARKETING AUTHORISATION NUMBER**

PA0979/038/003

## **9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorisation: 02 May 1997

Date of last renewal: 02 May 2007

## **10 DATE OF REVISION OF THE TEXT**

July 2021