

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

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

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains:

Amylmetacresol 0.6 mg

2,4-Dichlorobenzyl alcohol 1.2 mg

Excipients with known effects:

Glucose 1.10 g (1102 mg)/lozenge.

Sucrose 1.38 g (1384 mg)/lozenge.

Wheat Starch (containing gluten present in liquid glucose) 22.04 micrograms/lozenge.

Sulphites - Sulphur Dioxide (E220) present in liquid glucose 0.141 ppm/lozenge.

Flavouring fragrances containing citral, cinnamol, citranellol, eugenol, farnesol, geraniol, isoeugenol and linalool.

For the full list of excipients, see section 6.1

## 3 PHARMACEUTICAL FORM

Lozenge

A circular, biplanar red to purple lozenge with a characteristic warm taste of plum and ginger, embossed on both sides with strepsils brand icon.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For the symptomatic relief of mouth and throat infections.

### 4.2 Posology and method of administration

#### Posology

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.

**Adults and children (over 12 years):** One lozenge to be dissolved slowly in the mouth every 2-3 hours or as directed by a physician. It is recommended that the product should be used for a maximum of 3 days. Do not take more than 12 lozenges in 24 hours.

**Elderly:** There is no need for dosage reduction in the elderly.

Not suitable for children under 12 years.

#### Method of administration

For oral administration.

### 4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Patients with rare hereditary problems of fructose intolerance, glucose, galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

#### 4.4 Special warnings and precautions for use

Keep all medicines out of the sight and reach of children.

Consult your doctor if symptoms persist, if anything unusual happens or if symptoms have worsened within 3 days.

This medicine contains only very low levels of gluten (from wheat starch). It is regarded as 'gluten-free' and is very unlikely to cause problems if you have coeliac disease. One lozenge contains no more than 22.04 micrograms of gluten. If you have a wheat allergy (different from coeliac disease), you should not take this medicine.

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

Contains 1.10 g glucose and 1.38 g sucrose per lozenge. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

Contains sulphites – Sulphur Dioxide (E220) which may rarely cause severe hypersensitivity reactions and bronchospasm.

Also contains fragrances, which contain allergens: citral, cinnamol, citranellol, eugenol, farnesol, geraniol, isoeugenol and linalool which may cause allergic reactions.

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

No clinically significant interactions are known.

#### 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.

##### Breastfeeding

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

##### Fertility

No data are available regarding the effects on fertility.

#### 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, amylmetacresol and levomenthol 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

<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 the unlikely event of an overdose, serious side effects are not expected. Some gastrointestinal discomfort may be experienced.

### Management:

Treatment should be symptomatic.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

**Pharmacotheapeutic 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 in clinical studies with an onset in 5 minutes which lasts for up to 2 hours. Significantly more relief than non-medical lozenge was also demonstrated for up to 3 days treatment.

Strepsils lozenges have also been shown to significantly decrease post-operative 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 Warm lozenge base has a demulcent action providing throat soothing.

### 5.2 Pharmacokinetic properties

None stated.

### 5.3 Preclinical safety data

Not applicable.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Fruity Plum Flavour  
Soothing Cream Flavour  
Warm Sensation Flavour  
Tartaric acid  
Warm ginger spice flavour  
Anthocyanins (E163)  
Sucrose  
Glucose  
Medium Chain Triglycerides

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

2 years, for lozenges packed in blister strips within a carton.  
3 years, for lozenges packed in polypropylene tubes, with an 'in-use' shelf life of 3 months.

### 6.4 Special precautions for storage

Blister: Do not store above 25°C  
Tube: Do not store above 25°C. Keep the tube tightly closed in order to protect from moisture.

### 6.5 Nature and contents of container

A blister push-through tray of PVC/PVDC laminate heat-sealed to aluminium foil.

-24 lozenges (each blister tray contains 12 lozenges packed in a carton).  
-8 lozenges (one tray contains 8 lozenges in a wrap around cardboard carton with tamper-evident seal).  
-2 lozenges pack.

An injection moulded white pigmented polypropylene tube with a plastic spring and an injection moulded white polyethylene cap (containing white silica gel that is sealed with a white cardboard disc). The tube contains 10 lozenges.

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

PA0979/058/001

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

Date of first authorisation: 24<sup>th</sup> July 2009

Date of last renewal: 23<sup>rd</sup> July 2014

**10 DATE OF REVISION OF THE TEXT**

July 2021