

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1 NAME OF THE MEDICINAL PRODUCT**

Strepsils Citrus Flavour Lozenges

Strepsils Dry Throat Lozenges

### **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Amylmetacresol 0.6mg/lozenge

2,4-Dichlorobenzyl alcohol 1.2mg/lozenge

Excipient(s) with known effect:

- Isomalt
- Maltitol liquid
- Fragrance containing allergens – benzyl alcohol, citral, citronellol, d-limonene, geraniol and linalool (in the Lemon flavour)

For a full list of excipients, see section 6.1

### **3 PHARMACEUTICAL FORM**

A white to pale yellow, circular lozenge with a characteristic lemon taste and the Strepsils brand icon intagliated on both sides.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

As an antiseptic for the relief of sore throat and its associated pain.

#### **4.2 Posology and method of administration**

##### **Posology**

Use the lowest dose for the shortest duration necessary to relieve symptoms.

##### **Adults:**

One lozenge every 2-3 hours up to a maximum of 12 lozenges in 24 hours

Children over 6 years old:

As above for adults.

**Elderly:**

There is no need for dosage reduction in the elderly.

**Children under 6 years old:**

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

**Method of administration**

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

**4.3 Contraindications**

Strepsils Citrus Flavour Lozenges are contraindicated in persons who have previously shown hypersensitivity to any of the ingredients.

**4.4 Special warnings and precautions for use**

Not to be given to children under 6 years.

If symptoms persist, have not improved, or have worsened after 3 days, or if symptoms are accompanied by a high fever or headache consult a doctor or health care professional.

**Important information about some of the ingredients of this medicine:**

- Contains isomalt and maltitol syrup, which may have a mild laxative effect if several are taken a day. Patients with rare hereditary problems of fructose intolerance should not take this medicine.
- This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.
- This medicine contains fragrance with Benzyl Alcohol, Citral, Citronellol, d-Limonene, Geraniol and Linalool. Benzyl Alcohol, Citral, Citronellol, d-Limonene, Geraniol and Linalool may cause allergic reactions.

**4.5 Interaction with other medicinal products and other forms of interaction**

None known.

## 4.6 Fertility, pregnancy and lactation

### Pregnancy

There are no or limited amount of data from the use of amylmetacresol and 2,4-dichlorobenzyl alcohol.

As with all medicines care should be taken when using this product in pregnancy and medical advice sought if necessary.

### Breast-feeding

It is unknown whether 2,4-dichlorobenzyl alcohol, amylmetacresol or metabolites are excreted 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 or negligible influence on the ability to drive and use machines.

## 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.

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>ab1</sup>
Gastrointestinal Disorders	Not known	Glossodynia <sup>ab</sup> , oral discomfort <sup>ab</sup>

<sup>a</sup>2,4-dichlorobenzyl alcohol <sup>b</sup>amylmetacresol

<sup>1</sup> Hypersensitivity reactions may include rash, urticaria and angioedema, which may include swelling of the face, neck, throat or tongue that could affect breathing.

#### **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 the Yellow Card Scheme at: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

### **4.9 Overdose**

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

Overdosage should not present a problem other than gastrointestinal discomfort. Treatment should be symptomatic.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

**Pharmacotherapeutic group:** Throat Preparations; Antiseptics; **ATC Code:** R02AA03 Dichlorobenzyl alcohol.

2,4-Dichlorobenzyl alcohol and amylmetacresol have antiseptic properties.

### **5.2 Pharmacokinetic properties**

An oral bioavailability study conducted on Strepsils lozenges demonstrated a rapid release of 2,4-dichlorobenzyl alcohol and amylmetacresol into saliva with peak levels achieved within 3-4 minutes of sucking the lozenge. A doubling of saliva volume was observed within a minute\* and levels above baseline were maintained whilst the lozenge dissolved over approximately 6 minutes. Quantifiable amounts of actives were expectorated up to 20-30 minutes post dose; net recovery of actives was suggestive of a prolonged residency in mouth and throat mucosa.

### **5.3 Preclinical safety data**

There are no preclinical data available specific to the product.

## **6 PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Lemon flavour (fragrance containing allergens – benzyl alcohol, citral, citronellol, d-limonene, geraniol and linalool)

Saccharin sodium Ph Eur (E954)

Tartaric acid

Isomalt (Isomaltitol E 953)

Maltitol syrup (E965)

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

3 years

### **6.4 Special precautions for storage**

Do not store above 25°C

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

The lozenges are contained in a strip pack containing either 6, 8, 12, 16, 18, 20, 22, 24, 32 or 36 lozenges packed into a cardboard carton. Not all pack sizes may be marketed.

**6.6 Special precautions for disposal**

None

**7 MARKETING AUTHORISATION HOLDER**

Reckitt Benckiser Healthcare (UK) Limited

Dansom Lane

Hull

HU8 7DS

United Kingdom

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 00063/0462

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

28/09/2004 / 02/07/2009

**10 DATE OF REVISION OF THE TEXT**

29/12/2020