

## **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Strepsils Sore Throat and Blocked Nose Lozenges  
Strepsils Sore Throat and Cough Lozenges

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

Amylmetacresol BP	0.6mg
2,4-Dichlorobenzyl alcohol HSE	1.2mg
Levomenthol natural or synthetic EP	8.0mg

Excipient(s) with known effect:

- Liquid Glucose (containing Wheat Starch (containing Gluten) and Sulphites – Sulphur Dioxide (E220))
- Liquid Sucrose
- D-Limonene (present in Eucalyptus oil)

For a full list of excipients, see section 6.1.

### **3 PHARMACEUTICAL FORM**

A blue circular lozenge with a characteristic taste.

### **4 CLINICAL PARTICULARS**

#### **4.1 Therapeutic indications**

For the symptomatic relief of mouth and throat infections, dry, irritating cough associated with the common cold and nasal congestion.

#### **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**

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, consult a doctor or health care professional.

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

- This medicine contains sucrose (1.496g per lozenge) and glucose (1.013g per lozenge). Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
- 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 20.26 micrograms of gluten. If you have 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'.
- This medicine contains Sulphites – Sulphur Dioxide (E220) (present in liquid Glucose) which may rarely cause severe hypersensitivity reactions and bronchospasms.
- This medicine contains fragrance with d-Limonene (Eucalyptus oil), d-limonene may cause allergic reactions.

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

No clinically significant interactions are known.

#### 4.6 Fertility, pregnancy and lactation

##### Pregnancy

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

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, levomenthol 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>
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<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**

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.

Menthol has a mild local anaesthetic action on the throat and also relieves the symptoms of cough and nasal congestion.

## **5.2 Pharmacokinetic properties**

None available.

## **5.3 Preclinical safety data**

None available.

## **6.1 List of excipients**

Liquid sucrose, liquid glucose (containing Wheat Starch (containing Gluten) and Sulphites – Sulphur Dioxide (E220)), tartaric acid gran 572 GDE, eucalyptus oil (containing d-Limonene), indigo carmine BP '73 (E132), water.

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

36 months for lozenges packed in blister strips within a carton.

18 months for blister pack attached to a stencilled card.

## **6.4 Special precautions for storage**

Do not store above 25°C.

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

A blister push-through pack consisting of hard temper aluminium foil heat sealed to a PVC/PVDC blister. The tray contains an appropriate number of lozenges to give pack sizes of 6, 8, 10, 12, 16, 20, 24, 32 and 36 lozenges in a cardboard carton.

A blister push-through pack consisting of hard-temper aluminium foil heat-sealed to a PVC/PVDC blister. Two, four or six blisters are attached to a stencilled card.

## **6.6 Special precautions for disposal**

Not applicable.

**7      MARKETING AUTHORISATION HOLDER**

Reckitt Benckiser Healthcare (UK) Ltd  
Slough  
SL1 3UH

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 00063/0398

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

06/04/2010

**10     DATE OF REVISION OF THE TEXT**

04/05/2021