

# SUMMARY OF PRODUCT CHARACTERISTICS

## 1 NAME OF THE MEDICINAL PRODUCT

Strepsils Warm Lozenges

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Amylmetacresol 0.6 mg

2,4-Dichlorobenzyl alcohol 1.2mg

Excipient(s) with known effect:

- Glucose (containing wheat starch (containing gluten), sulphites – Sulphur Dioxide (E220))
  - Sucrose
  - Warm Ginger spice flavour (contains Citral, Citranellol, Eugenol, Farnesol, Geraniol, Isoeugenol and Linalool)
  - Warm Sensation flavour (contains Cinnamal, Eugenol and Citronellol)
- For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

A red to purple coloured circular lozenge with a characteristic taste of warm plum and ginger. Strepsils brand icon is intagliated on both sides.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

For the symptomatic relief of mouth and throat infections.

### 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, symptoms have not improved, or have worsened after 3 days consult a doctor or health care professional.

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

- 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 22.04 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 fragrance with Citral, Cinnamal, Citranellol, Eugenol, Farnesol, Geraniol, Isoeugenol and Linalool. Citral, Cinnamal, Citranellol, Eugenol, Farnesol, Geraniol, Isoeugenol and Linalool may cause allergic reactions.
- This medicine contains Sulphites – Sulphur Dioxide (E220) present in liquid glucose, which may rarely cause severe hypersensitivity reactions and bronchospasm.

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

No clinically significant interactions are known.

**4.6 Pregnancy and lactation**

**Pregnancy**

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

<b>System Organ Class</b>	<b>Frequency</b>	<b>Adverse Events</b>
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**

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**

Pharmacokinetically the active ingredients, when present in a dosage form such as a lozenge, will exert their desired effect locally on the oropharynx.

#### **5.3 Preclinical safety data**

There are no pre-clinical data of relevance to the prescriber, which are additional to that included in other sections of the SPC.

### **6 PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Enocianin dye (E163) (containing sodium),  
Fruity Plum Flavour (contains Propylene Glycol)  
Soothing Cream Flavour (contains Glycerol and Propylene Glycol)  
Tartaric acid  
Warm Sensation Flavour (containing Cinnamal, Eugenol and Citronellol)  
Warm Ginger Spice Flavour (containing Citral, Citranellol, Eugenol, Farnesol,  
Geraniol, Isoeugenol and Linalool)  
Medium chain triglycerides  
Sucrose  
Glucose (containing wheat starch (containing gluten) and sulphites – Sulphur dioxide (E220))

## **6.2 Incompatibilities**

Not applicable.

## **6.3 Shelf life**

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

24 months for lozenges packed in polypropylene tube, with an in use shelf-life of 'use within 3 months of opening'.

## **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 15 or 20µm hard temper aluminium foil heat-sealed to a 250µm PVC/40gms or PVC/90gms PVDC blister. The tray contains an appropriate number of lozenges to give pack sizes of 6, 8, 10, 12, 16, 20, 24, 32, 36 and 720 lozenges in a cardboard carton or a flow wrap composed of PET/aluminium foil/polyethylene.

A blister push-through pack consisting of 15 or 20µm hard temper aluminium foil heat-sealed to a 250µm PVC/40gms or PVC/90gms PVDC blister. The tray contains an appropriate number of lozenges to give a pack size of 8 lozenges in a wrap around cardboard carton with tamper-evident seal.

An injection moulded white pigmented polypropylene tube with 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**

Not applicable.

## **7 MARKETING AUTHORISATION HOLDER**

Reckitt Benckiser healthcare (UK) Limited  
103 – 105 Bath Road  
Slough

Berkshire  
SL1 3UK  
UK.

**8      MARKETING AUTHORISATION NUMBER(S)**

PL 00063/0468

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

11/02/2010

**10     DATE OF REVISION OF THE TEXT**

07/05/2024