

# **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Strepsils Extra Blackcurrant Lozenges  
Strepsils Extra Triple Action Blackcurrant Lozenges  
Strepsils Extra Strength Blackcurrant Lozenges

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each lozenge contains Hexylresorcinol 2.4mg  
Excipient(s) with known effect:  
Glucose  
Fragrance containing allergens - d-Limonene and Linalool\*\*  
Carmoisine (E122)  
Sucrose  
Sulphites – Sulphur Dioxide (E220)\*  
Wheat starch (containing Gluten)\*  
Propylene glycol \*\*

\* present in liquid glucose

\*\* present in blackcurrant flavour

For excipients see Section 6.1

## **3 PHARMACEUTICAL FORM**

Lozenge

A round purple lozenge

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

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

## 4.2 Posology and method of administration

For oral administration.

Adults, the elderly and children 6 years and over: One lozenge dissolved slowly in the mouth every three hours or as required.  
Do not take more than 12 lozenges in 24 hours.

Not to be given to children under 6 years.

## 4.3 Contraindications

Hypersensitivity to any of the ingredients.

## 4.4 Special warnings and precautions for use

The label will convey:

Keep out of the reach and sight of children.

If symptoms persist consult your doctor.

Not to be given to children under 6 years.

### **Important information about some of the ingredients of 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 22.42 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 d-Limonene and Linalool.  
d-Limonene and Linalool may cause allergic reactions.
- This medicine contains carmoisine (E122) which may cause allergic reactions
- This medicine contains Sulphites – Sulphur Dioxide (E220) – present in liquid glucose which may rarely cause severe hypersensitivity reactions and bronchospasm.
- Patients with rare glucose-galactose malabsorption should not take this medicine
- Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

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

None known.

#### **4.6 Pregnancy and lactation**

There is lack of evidence of safety of the product in human pregnancy and in animals, but hexylresorcinol has been used widely in lozenges for many years without apparent ill consequence. However, as with all medicines, caution should be exercised during pregnancy and lactation.

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

None known.

#### **4.8 Undesirable effects**

<b>System Organ Class</b>	<b>Frequency</b>	<b>Adverse Events</b>
Immune System Disorders	Not known	Hypersensitivity <sup>1</sup>

<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**

Hexylresorcinol overdose may cause minor gastrointestinal irritation. Treatment would be withdrawal of the product and symptomatic measures as appropriate.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

Hexylresorcinol is a local anaesthetic for topical use on the mucous membranes of the mouth and throat. Mild antiseptic activity has also been demonstrated. The product base has a demulcent action.

### **5.2 Pharmacokinetic properties**

Pharmacokinetic considerations do not arise since the pharmacological action is local to the oro-pharyngeal cavity.

### **5.3 Preclinical safety data**

There are no preclinical data of relevance additional to those already included in other sections of the SPC.

## **6.1 List of excipients**

Liquid sucrose  
Liquid glucose (prepared from wheat starch (containing gluten) and Sulphites – Sulphur Dioxide)  
Blackcurrant flavour (containing Propylene glycol, d-Limonene and Linalool)  
Levomenthol  
Carmoisine (E122)  
Patent blue V (E131)

## **6.2 Incompatibilities**

Not applicable

**6.3 Shelf life**

36 months for the unopened blister pack

**6.4 Special precautions for storage**

Do not store above 25°C. Store in the original packaging. Keep in the outer carton.

**6.5 Nature and contents of container**

Blister packs of 250 micron PVC/coated 40gsm PVDC with 20 micron hard temper aluminium foil heat-sealed to the PVC/PVDC blister. The tray contains an appropriate number of lozenges to give a pack sizes of 2, 4, 6, 12, 16, 24, 32, 36 and 48.

8 lozenges in a blister in a carton or a flow wrap outer composed of PET/aluminium foil/polyethylene.

**6.6 Special precautions for disposal**

None specific to the product/pack.

**7 MARKETING AUTHORISATION HOLDER**

Reckitt Benckiser Healthcare (UK) Ltd  
Slough  
SL1 3UH

**8 MARKETING AUTHORISATION NUMBER(S)**

PL 00063/0392

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

19/03/2010

**10 DATE OF REVISION OF THE TEXT**

23/08/2021