

# **SUMMARY OF PRODUCT CHARACTERISTICS**

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

Strepsils Triple Action Honey & Lemon Flavour 2.4mg Lozenges

## **2 QUALITATIVE AND QUANTITATIVE COMPOSITION**

Hexylresorcinol Ph Eur 2.4mg

Also contains the following excipients:

Propylene Glycol (E1520)

Liquid Sucrose

Liquid Glucose (Wheat starch (containing Gluten) and Sulphites – Sulphur Dioxide (E220))

Honey and Lemon Flavour (containing Bergamot oil (containing bergapten), Citral, Citronellol, d-Limonene, Farnesol, Geraniol and Linalool).

For a full list of excipients, see section 6.1

## **3 PHARMACEUTICAL FORM**

Lozenge

## **4 CLINICAL PARTICULARS**

### **4.1 Therapeutic indications**

As an antiseptic, demulcent 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:

Do not exceed the stated dose.

Keep out of the reach of children.

Not to be given to children under 6 years.

This product is unsuitable hereditary fructose intolerance, glucose-galactose malabsorption syndrome, or sucrase-isomaltase deficiency.

Important information about some of the ingredients of this medicine:

- This medicine contains Glucose (1125 mg per lozenge) and Sucrose (1413 mg 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 Sulphites – Sulphur Dioxide present in liquid glucose which may rarely cause severe hypersensitivity reactions and bronchospasm.
- 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 22.50 micrograms of gluten. If you have wheat allergy (different from coeliac disease) you should not take this medicine.
- This medicine contains 3.12 mg Propylene glycol in each lozenge.
- This medicine contains fragrance with Citral, Citronellol, d-Limonene, Farnesol, Geraniol and Linalool. Citral, Citronellol, d-Limonene, Farnesol, Geraniol and Linalool may cause allergic reactions.
- This medicine contains Bergamot oil (present in Lemon and Honey flavour) which may increase sensitivity to UV light (natural and artificial sunlight).

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

None known.

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

There is a lack of evidence of safety of the product in human pregnancy, 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**

No adverse effects 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 overdosage 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 oropharyngeal cavity.

### **5.3 Preclinical safety data**

There are no pre-clinical data available specific to the product.

## **6.1 List of Excipients**

Liquid Sucrose, Liquid Glucose (containing wheat starch (containing Gluten), and sulphites – Sulphur Dioxide (E220)), Propylene Glycol (E1520), Honey and Lemon Flavour (containing Bergamot oil (containing bergapten), Citral, Citronellol, d-Limonene, Farnesol, Geraniol and Linalool).

## **6.2 Incompatibilities**

Not applicable

## **6.3 Shelf life**

24 months

**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 90 gsm PVDC with 20 micron hard temper aluminium foil, heat sealed to the PVC/PVDC blister containing 6, 8, 10, 12, 16, 20, 24, 32 or 36 lozenges in a carton.

**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 00063/0394

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

06/04/2010

## **10 DATE OF REVISION OF THE TEXT**

09/03/2021