# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Strepsils Extra Blackcurrant Lozenges

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains hexylresorcinol 2.4 mg.

Excipients with known effects:
Each lozenge contains Glucose 1.121 g, Sucrose 1.408 g, Propylene Glycol 10.8 mg, Wheat Starch 22.42 µg, Sulphur Dioxide (E220) 0.143 ppm and Carmoisine (E122) 0.130 ppm.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Lozenge
Circular 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

**Posology**
**Adults**: One lozenge every three hours or as required. Do not take more than 12 lozenges in 24 hours. Duration of therapy should be limited to a maximum of 3 days.

**Paediatric Population:**
Children of 6 years and over: Same as for adults.

Not to be given to children under 6 years.

**Elderly Population:**
No dosage adjustment is considered necessary in the elderly.

**Method of administration**
For oral administration. Allow the lozenge to dissolve slowly in the mouth.

### 4.3 Contraindications

Hypersensitivity to hexylresorcinol or to any of the excipients listed in section 6.1.

### 4.4 Special warnings and precautions for use

If symptoms do not improve or worsen within 3 days, consult a healthcare professional.
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 a 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 also contains 1.121 g glucose and 1.408 g sucrose per lozenge. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-insomaltase insufficiency should not take this medicine.

This medicine contains 10.8 mg propylene glycol (present in blackcurrant flavour) per lozenge.
This medicine contains fragrance with d-Limonene and Linalool which may cause allergic reactions.
Also contains sulphites - Sulphur Dioxide (E220) - present in liquid glucose which may rarely cause severe hypersensitivity reactions and bronchospasm, and Azo colouring agent Carmoisine (E122) which may cause allergic reactions.

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

None known.

**4.6 Fertility, pregnancy and lactation**

There is a lack of evidence of safety of the product in human pregnancy and in animals, but hexylresorcinols has been widely used in lozenges for many years without apparent ill consequence.

**Pregnancy**
The product should be used with caution during pregnancy. There are no or limited amount of data from the use of hexylresorcinol in pregnant women. No effects during pregnancy are anticipated.

**Breast-feeding**
The product should be used with caution during breast-feeding. It is unknown whether hexylresorcinol/metabolites are excreted in human milk. No effects on the breastfed newborn/infant are anticipated.

**Fertility**
There are no data available regarding the use of hexylresorcinol on male or female fertility. No effects on fertility are anticipated.

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

The product has no or negligible influence on the ability to drive and use machines.

**4.8 Undesirable effects**

Adverse events which have been associated with hexylresorcinol are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common (≥1/10); Common (≥1/100 and <1/10); Uncommon (≥1/1000 and <1/100); Rare (≥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[1] |

**Description of Selected Adverse Reactions**
[1] 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

**4.9 Overdose**

Symptoms
Hexylresorcinol over-dosage may cause minor gastrointestinal irritation.

Management

Treatment would be withdrawal of the product and symptomatic measures as appropriate.

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

**Pharmacotherapeutic group:** Throat preparations, antiseptics; **ATC Code:** R02AA12

Hexylresorcinol is a phenol derivative and local anaesthetic for topical use on the mucous membranes of the mouth and throat. The local anaesthetic-like properties of hexylresorcinol are due, at least in part, to sodium channel-blocking effects. 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-pharangeal cavity.

### 5.3 Preclinical safety data

There is no pre-clinical data of relevance additional to those already included in other section of the SPC.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

Liquid Glucose (wheat starch and sulphur dioxide)
Liquid Sucrose
Blackcurrant flavour (containing propylene glycol)
Levomenthol
Carmoisine edicol (E122)
Patent Blue V (E131)

### 6.2 Incompatibilities

Not applicable.

### 6.3 Shelf life

3 years.

### 6.4 Special precautions for storage

Do not store above 30°C. Store in the original packaging.

### 6.5 Nature and contents of container

Blister packs of 250 micron PVC coated 40 gsm PVdC with 20 micron hard temper aluminium foil, heat sealed to the PVC/PVDC blister.
24 lozenges in two blister strips in a carton.

### 6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

## 7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

## 8 MARKETING AUTHORISATION NUMBER

PA0979/042/001

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

Date of first authorisation: 10 June 2005

Date of last renewal: 10 June 2010

## 10 DATE OF REVISION OF THE TEXT

August 2021