Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Strepsils Sore Throat & Blocked Nose Lozenges Amylmetacresol 0.6mg 2,4-Dichlorobenzyl Alcohol 1.2mg Levomenthol 8.0mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients

Amylmetacresol	0.6	mg
2, 4-Dichlorobenzyl alcohol	1.2	mg
Levomenthol	8.0	mg

Excipients with known effects:
Glucose 1.013 g (1013 mg)/lozenge.
Sucrose 1.496 g (1496 mg)/lozenge.
Wheat Starch (containing gluten, present in liquid glucose) 20.26 micrograms/lozenge.
Eucalyptus oil fragrance containing d-Limonene.
Sulphites - Sulphur Dioxide (E220), present in liquid glucose 0.130 ppm/lozenge.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Lozenge.

A blue, circular lozenge with a characteristic taste, embossed on both sides with strepsils brand icon.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of mouth and throat infections and nasal congestion.

4.2 Posology and method of administration

Posology
The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. It is recommended that the product should be used for a maximum of 3 days.

Adults;
One lozenge every 2-3 hours. Do not take more than 12 lozenges in 24 hours.

Paediatric population:
Children over 6 years of age:
As above for adults.

Children under 6 years of age:
Not suitable for children under 6 years (see section 4.4)

Elderly:
There is no need for dosage reduction in the elderly.

Method of administration:
For oromucosal administration, To be dissolved slowly in the mouth.

4.3 Contraindications

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

4.4 Special warnings and precautions for use

This product is not recommended for young children due to a risk of choking.
Consult your doctor if symptoms persist or if anything unusual happens.

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 also contains 1.013 g glucose and 1.496 g sucrose per lozenge. This should be taken into account in patients with diabetes mellitus. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-insomaltase insufficiency should not take this medicine.

Fragranced with d-Limonene which may cause allergic reactions.

Also contains sulphites (Sulphur Dioxide, E220) which may rarely cause severe hypersensitivity reactions and bronchospasm.

4.5 Interaction with other medicinal products and other forms of interactions

No clinically significant interactions are known.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of amylmetacresol, 2,4-dichlorobenzyl alcohol and levomenthol in pregnant women. As a precautionary measure, it is preferable to avoid the use of Strepsils during pregnancy.

Breast-feeding
There is insufficient information on the excretion of amylmetacresol, 2,4-dichlorobenzyl alcohol or levomenthol metabolites in human milk. A risk to the newborn/infants cannot be excluded.

Fertility
Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

4.7 Effects on ability to drive and use machines

No adverse events are known.

4.8 Undesirable effects

The list of the following adverse effects relates to those experienced with 2,4 dichlorobenzyl alcohol and amylmetacresol and levomenthol at OTC doses, in short term use. In the treatment of chronic conditions, under long-term treatment additional adverse effects may occur. Adverse events which have been associated with 2,4-dichlorobenzyl alcohol, amylmetacresol and levomenthol 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]
Gastrointestinal Disorders	Not known	Abdominal pain, nausea, oral discomfort
Skin and Subcutaneous Tissue Disorders	Not known	Rash

Description of Selected Adverse Reactions

[1] Hypersensitivity reactions may present in the form of rash, angioedema, urticaria, bronchospasms and hypotension with syncope.

[2] Oral discomfort may present in the form of throat irritation, oral paraesthesia, oedema of the mouth and glossodynia.

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 Pharmacovigilance Section, Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

Symptoms:
Overdosage should not present a problem other than gastrointestinal discomfort.

Management:
Treatment should be symptomatic.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Throat Preparations; Antiseptics**; ATC Code:** R02AA03 Dichlorobenzyl alcohol.

Amylmetacresol and 2, 4-Dichlorobenzyl alcohol have antiseptic properties.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

No data available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tartaric Acid
Eucalyptus Oil (containing d-Limonene)
Indigo Carmine (E132)
Liquid Sucrose
Liquid Glucose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

The lozenges are contained in a strip pack of 250 micron PVC/coated 40 gsm PVDC with 20 micron hard temper aluminium foil, containing either 2, 24 or 36 lozenges packed in a cardboard 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

PA0979/060/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 30th January 1991

Date of last renewal: 30th January 2006

10 DATE OF REVISION OF THE TEXT

July 2021