

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

For excipients, see 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.

4.5 Interaction with other medicinal products and other forms of interaction

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 ($\geq 1/10$); 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.

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Not known	Hypersensitivity ^{ab}
Gastrointestinal Disorders	Not known	Abdominal pain ^{ab} , nausea ^{ab} , oral discomfort ^{ab}
Skin and Subcutaneous Tissue Disorders	Not known	Rash ^{ab}

^a2,4-dichlorobenzyl alcohol, ^bamylmetacresol

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

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.

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
Indigo Carmine (E132)
Solids from
Liquid Sugar Demineralised or Liquid Sugar

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 or 24 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

February 2016