

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Strepsils Cool Lozenges
2,4-Dichlorobenzyl Alcohol 1.2mg
Amylmetacresol 0.6mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains:

2, 4-Dichlorobenzyl alcohol	1.2 mg
Amylmetacresol	0.6 mg

Excipients: Each lozenge also contains 1.4g sucrose and 1.1g glucose.

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Lozenge
White to pale yellow coloured Lozenge with a characteristic taste of cool mint, embossed on both sides with Strepsils brand icon.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of mouth and throat infections.

4.2 Posology and method of administration

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

Adults: One lozenge every 2-3 hours. No more than 12 lozenges per day.

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

Paediatric population: Children 12 years and over: One lozenge every 2-3 hours. No more than 8 lozenges per day.

Children under 12 years: Not suitable for children under 12 years.

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.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltose insufficiency should not take this medicine.

4.4 Special warnings and precautions for use

Consult your doctor if symptoms persist or if anything unusual happen.
Not suitable for children under 12 years.

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 newborns/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 effects are known.

4.8 Undesirable effects

The list of the following adverse effects relates to those experienced with 2,4- dichlorobenzyl alcohol, 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

Occasionally hypersensitivity reactions.

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

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

Mechanism of action

2, 4-Dichlorobenzyl alcohol and amylmetacresol are antiseptics and possess antibacterial, antifungal and antiviral properties. Both AMC and DCBA also reversibly block depolarisation-induced ion channels in a similar way to local anaesthetics. When the two active agents are combined, a synergistic antibacterial action is observed leading to the reduced combined dose used in Strepsils lozenges.

Clinical efficacy and safety

Evidence of an analgesic effect for Strepsils in reducing throat soreness, providing pain relief and relief from difficulty in swallowing has been demonstrated to clinical studies with an onset in 5 minutes which lasts for up to 2 hours. Significantly more relief than nonmedical lozenge was also demonstrated for up to 3 days treatment.

Strepsils lozenge have also been shown to significantly decrease postoperative throat soreness and hoarseness 20 minutes and 24 hours after intubation.

A study in children (6-16 years) with acute and recurring chronic sore throat demonstrates a reduction in subjective and objective signs of sore throat over 3 days.

Strepsils Cool lozenge base has a demulcent action providing throat soothing.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Xylitol
Cool Mint Sensation Flavour (Contains propylene glycol)
Levomenthol
Spearmint
Eucalyptus oil
Liquid Sucrose
Liquid Glucose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years. (for lozenges packed in blister strips within a carton)

6.4 Special precautions for storage

Do not store above 25°C. (blisters)

6.5 Nature and contents of container

A blister push-through tray of PVC/PVDC laminate heat-sealed to aluminium foil.

24 lozenges (each blister tray contains 12 lozenges packed in a carton).

8 lozenges (one tray contains 8 lozenges in a wrap around cardboard carton with tamper-evident seal).

2 lozenges pack.

Not all pack sizes may be marketed.

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

PA0979/038/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25 January 1985

Date of last renewal: 25 January 2010

10 DATE OF REVISION OF THE TEXT

April 2017