Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Strepsils Lozenges for Adults and Children over Six
Amylmetacresol 0.6 mg
2,4-Dichlorobenzyl alcohol 1.2 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains amylmetacresol 0.6 mg and 2,4-dichlorobenzyl alcohol 1.2 mg.

Each lozenge also contains the following excipients:
Maltitol syrup 457.6 mg
Isomalt 1830.4 mg

For a full list of excipients, see Section 6.1.

3 PHARMACEUTICAL FORM

Lozenge.

Pink, circular lozenge with a characteristic strawberry taste, embossed on both sides with Strepsils brand icon.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Strepsils Lozenges for Adults and Children over Six are indicated for the symptomatic relief of mouth and throat infections including sore throat.

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.

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

Strepsils Lozenges for Adults and Children over Six are contraindicated in persons who have previously shown 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.

Patients with rare hereditary problems of fructose intolerance should not take this medicine.
This product contains isomalt and maltitol syrup which may have a mild laxative effect if several lozenges are taken a day.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

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 and 2,4-dichlorobenzyl alcohol 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 Arnylmetacresol or 2,4-Dichlorobenzyl alcohol 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 and amylmetacresol 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
Gastrointestinal Disorders	Not known	Abdominal pain, nausea, oral discomfort
Skin and Subcutaneous Tissue Disorders	Not known	Rash

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

In view of the nature and presentation of Strepsils Lozenges for Adults and Children over Six , accidental or deliberate overdosage is highly unlikely.

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 Lozenge for Adults and Children over 6 base has a demulcent action providing throat soothing.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Strawberry flavour 052312B
Pink Antho (E163)
Sodium saccharin (E954)
Tartaric acid

Isomalt (E953)
Maltitol syrup (E965)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Two years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

A blister push-through pack consisting of a hard temper aluminium foil heat sealed to a PVC/PVDC blister. Each blister contains 6, 8, 10, 12, 16, 20 or 24 lozenges. Two trays are packed in a carton or for two lozenge sample two blisters are attached to a stencilled card.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser
7 Riverwalk
Citywest Business Campus
Dublin 24

8 MARKETING AUTHORISATION NUMBER

PA0979/062/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd June 2011

Date of last renewal: 3rd June 2016

10 DATE OF REVISION OF THE TEXT

July 2017