Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Strepsils Original Lozenges
Amylmetacresol 0.6 mg
2, 4-dichlorobenzyl alcohol 1.2 mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains:
Amylmetacresol 0.6 mg
2,4-Dichlorobenzyl alcohol 1.2 mg

Also contains glucose 1g, sucrose 1.5g, carmoisine (E122) and Ponceau 4R (E124). For a full list excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lozenge
A circular, biplanar red lozenge with an aniseed odour, embossed on both sides with strepsils brand icon.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For mouth and throat infections

4.2 Posology and method of administration

Adults and children (over 6 years): One lozenge to be dissolved slowly in the mouth every 2-3 hours or as directed by a physician. Do not take more than 12 lozenges in 24 hours. It is recommended that the product should be used for a maximum of 3 days.

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

Not suitable for children under 6 years.

For oral administration.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Keep all medicines out of reach of children.

Consult your doctor if symptoms persist or if anything unusual happens.

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

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions are known.

4.6 Fertility, pregnancy and lactation

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. Animal studies do not indicate or indirect harmful effects with respect to reproductive toxicity. As a precautionary measure, it is preferable to avoid the use of Strepsils during pregnancy.

There is insufficient information on the excretion of amylmetacresol or 2,4-dichlorobenzyl alcohol metabolites in human milk.

4.7 Effects on ability to drive and use machines

No adverse effects are known.

4.8 Undesirable effects

Occasionally hypersensitivity 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, 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

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

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Star Anise oil
Peppermint oil
Levomenthol
Tartaric acid
Ponceau 4R (E124)
Carmoisine (E122)
Sucrose
Glucose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25ºC.

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

PA0979/057/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 24th July 2009

10 DATE OF REVISION OF THE TEXT

May 2015