Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Strepsils Honey & Lemon Lozenges Amylmetacresol 0.6mg 2,4-Dichlorobenzyl alcohol 1.2mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains Amylmetacresol 600 micrograms and 2, 4-Dichlorobenzyl alcohol 1.2 mg.

Excipients with known effects:
Glucose 0.98 g (976 mg)/lozenge.
Sucrose 1.44 g (1441 mg)/lozenge.
Invert Sugar (honey) 100.9 mg/lozenge.
Wheat Starch (containing gluten present in liquid glucose) 19.52 micrograms/lozenge.
Sulphites - Sulphur Dioxide (E220) present in liquid glucose 0.125 ppm/lozenge.
Lemon flavour fragrance containing citral, d-Limonene, geraniol and linalool.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lozenge

A yellow circular lozenge with a taste of honey and lemon, 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

Posolgy

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 to be dissolved slowly in the mouth 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.

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

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 19.52 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 0.98 g glucose, 1.44 g sucrose and 100.9 mg invert sugar per lozenge. This should be taken into account in patients with diabetes mellitus. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-insomaltase insufficiency should not take this medicine.

Lemon flavour fragranced with citral, d-Limonene, geraniol and linalool which may cause allergic reactions.

Also contains sulphites (sulphur dioxide E220) present in liquid glucose 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 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
It is unknown whether 2,4-dichlorobenzyl alcohol, amylmetacresol or metabolites are excreted in human milk. A risk to the newborns/infants cannot be excluded.

Fertility
No data are available regarding the effects on fertility.
However, 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 and amylmetacresol 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[2]
Skin and Subcutaneous Tissue Disorders	Not known	rash

[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 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

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.

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 Honey and Lemon lozenge base has a demulcent action providing throat soothing.

5.2 Pharmacokinetic properties

None available.

5.3 Preclinical safety data

None available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Honey
Tartaric Acid
Peppermint Oil
Terpeneless Lemon Oil (containing citral, d-Limonene, geraniol and linalool)
Quinoline yellow (E104)
Sucrose
Glucose Syrup

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years for 36 lozenge pack, 24 lozenge pack and 8 lozenge pack
18 months for 2 lozenge pack
3 years for lozenges packed in polypropylene tube, with an in use shelf-life of 'use within 3 months of opening'.

6.4 Special precautions for storage

Blister pack: Do not store above 25°C.

Polypropylene tube – do not store above 25°C. Keep the tube tightly closed in order to protect from moisture.

6.5 Nature and contents of container

A blister push-through pack consisting of hard temper aluminium foil heat sealed to a PVC/PVDC blister.
24 lozenge pack: Each blister contains 12 lozenges.Two trays are packed in a carton.

36 lozenge pack: Each blister contains 12 lozenges. Three trays are packed in a carton.

8 lozenge pack: One tray contains 8 lozenges in a wrap around cardboard carton with tamper-evident seal.
2 lozenge sample pack: Two blisters are attached to a stencilled card.

10 lozenge tube: An injection moulded white pigmented polypropylene tube fitted with a plastic spring with an injection moulded white polyethylene cap (containing white silica gel that is sealed with a white cardboard disc).

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

PA0979/038/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16 October 1986
Date of last renewal: 16 October 2006

10 DATE OF REVISION OF THE TEXT

July 2021