SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Strepsils Menthol 1.2mg/0.6mg Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Amylmetacresol BP	0.6mg
2,4-Dichlorobenzyl alcohol HSE	1.2mg

Excipient(s) with known effect:

- Liquid Glucose (containing Wheat Starch (containing Gluten) and Sulphites – Sulphur Dioxide (E220)
- Liquid Sucrose
- Propylene Glycol (E1520)
- Fragrance containing allergens:
    - Spearmint flavour containing - Benzyl Alcohol, Cinnamyl Alcohol, Citral, Citranellol, d-Limonene, Eugenol and Linalool
    - Cool Mint Sensation Flavour containing – Linalool ad d-limonene
    - Eucalyptus oil containing d-limonene

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

White to pale yellow coloured lozenge with a characteristic taste of cool mint and the Strepsils brand icon intagliated on both sides

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For the symptomatic relief of mouth and throat infections.

4.2 Posology and method of administration

Posology
Use the lowest dose for the shortest duration necessary to relieve symptoms.

Adults: One lozenge to be dissolved slowly in the mouth every 2-3 hours up to a maximum of 12 lozenges in 24 hours.

Children over 12 years: One lozenge to be dissolved slowly in the mouth every 2-3 hours up to a maximum of 8 lozenges in 24 hours.

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

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

Method of administration
For oral administration. To be dissolved slowly in the mouth.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

If symptoms persist, have not improved, or have worsened after 3 days, consult a doctor or health care professional.

Important information about some of the ingredients of this medicine:

- This medicine contains sucrose (1.38 g per lozenge) and glucose (1.10 g per lozenge). Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
- 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 22.04 micrograms of gluten. If you have wheat allergy (different from coeliac disease) you should not take this medicine.
- This medicine contains 1.89 mg propylene glycol in each lozenge.
- This medicine contains fragrance with Benzyl Alcohol, Cinnamyl Alcohol, Citral, Citranellol, d-Limonene, Eugenol and Linalool. Benzyl Alcohol, Cinnamyl Alcohol, Citral, Citranellol, d-Limonene, Eugenol and Linalool may cause allergic reactions.
- This medicine contains Sulphites – Sulphur Dioxide (E220) (present in liquid Glucose) which may rarely cause severe hypersensitivity reaction and bronchospasm.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions are known.

4.6 Pregnancy and lactation

The safety of Strepsils Menthol 1.2mg/0.6mg Lozenges has not been established, therefore not recommended.

Pregnancy
There are no or limited amount of data from the use of amylmetacresol, 2,4-dichlorbenzyl alcohol and levomenthol.

Breast-feeding
It is unknown whether 2,4-dichlorobenzyl alcohol, amylmetacresol, levomenthol 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.

4.7 Effects on ability to drive and use machines

No or negligible influence on the ability to drive and use machines.

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.

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[ab1]
Gastrointestinal Disorders	Not known	Glossodynia[ab], oral discomfort[ab]

[a]2,4-dichlorobenzyl alcohol [b]amylmetacresol

[1] Hypersensitivity reactions may include rash, urticaria and angioedema, which may include swelling of the face, neck, throat or tongue that could affect breathing.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

Overdose 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.

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

5.2 Pharmacokinetic properties

Pharmacokinetically the active ingredients, when present in a dosage form such as a lozenge, will exert their desired effect locally on the oropharynx.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber, which are additional to that included in other sections of the SPC.

6.1 List of excipients

Xylitol
Cool Mint Sensation Flavour (contains Propylene glycol (E1520), linalool and d-limonene).
Levomenthol
Spearmint Flavour (containing Benzyl Alcohol, Cinnamyl Alcohol, Citral, Citranellal, Eugenol, d-Limonene and Linalool)
Eucalyptus oil (containing d-limonene)
Liquid Sucrose
Liquid Glucose (containing Wheat Starch (containing Gluten) and Sulphites – Sulphur Dioxide (E220)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months for lozenges packed in blister strips within a carton.

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 15 or 20µm hard temper aluminium foil heat-sealed to a 250µm PVC/40gms PVDC blister.
The tray contains an appropriate number of lozenges to give pack sizes of **4**, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 36, 40, 44, 48 and 720 lozenges in a cardboard carton or a flow wrap composed of PET/aluminium foil/polyethylene

A blister push-through pack consisting of 15 or 20µm hard temper aluminium foil heat-sealed to a 250µm PVC/40gms PVDC blister. The tray contains an appropriate number of lozenges to give a pack size of 8 lozenges in a wrap around cardboard carton with tamper-evident seal.

An injection moulded white pigmented polypropylene tube with an injection moulded white polyethylene cap (containing white silica gel that is sealed with a white cardboard disc). The tube contains 10 lozenges.

20 lozenges consisting of a bundled pack of 2 tubes of 10 lozenges each.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Ltd
Slough
SL1 3UH

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0469

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

11/02/2010

10 DATE OF REVISION OF THE TEXT

04/03/2021