SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Strepsils Strawberry Sugar Free Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients
Amylmetacresol 0.6mg/lozenge
2,4-Dichlorobenzyl alcohol 1.2mg/lozenge
Excipient(s) with known effect:
Propylene glycol (present in strawberry flavour)
Fragrance containing allergens – Benzyl Alcohol (present in strawberry flavour)
Isomalt
Maltitol syrup

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lozenge

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

As an antiseptic for the relief of sore throat and its associated pain.

4.2 Posology and method of administration

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

Adults:
One lozenge every 2-3 hours up to a maximum of
12 lozenges in 24 hours.

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

Children over 6 years old:
As above for adults.

Children under 6 years old:
Not suitable for children under 6 years (see section 4.4).

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

4.3 Contraindications

Strepsils Strawberry Sugar Free Lozenges are contraindicated in persons who have previously shown hypersensitivity to any of the ingredients.
The product contains a small amount of butylated hydroxyanisole (BHA; E320)

4.4 Special warnings and precautions for use

Not to be given to children under 6 years.

If symptoms persist have not improved, or have worsened after 3 days, or if symptoms persist or are accompanied by a high fever or headache, consult a doctor or health care professional.
Important information about some of the ingredients of this medicine:

- Contains isomalt and maltitol syrup, which may have a mild laxative effect if several are taken a day. Patients with rare hereditary problems of fructose intolerance should not take this medicine.
- This medicine contains 7.30 mg propylene glycol (present in strawberry flavour) in each lozenge.
- This medicine contains fragrance Benzyl Alcohol. Benzyl Alcohol may cause allergic reactions.
- This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially ‘sodium-free’.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

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

As with all medicines care should be taken when using this product in pregnancy and medical advice sought if necessary.

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.

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

In view of the nature and presentation of Strepsils Strawberry Sugar Free Lozenges, 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.

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

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

There are no preclinical data available specific to the product.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Flav P Strawberry Flavour (containing propylene glycol, Fragrance allergen Benzyl Alcohol)
Anthocyanins (E163)
Saccharin sodium Ph Eur (E954)
Tartaric acid Ph Eur
Isomalt (Isomaltitol E953)
Maltitol syrup (E965)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

The lozenges are contained in a strip pack containing either 6, 8, 12, 16, 20, 24, 32 or 36 lozenges packed into a cardboard carton.

The lozenges are contained in a strip pack containing 8 lozenges packed into a wrap around cardboard carton with tamper-evident seal.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Ltd
Slough
SL1 3UH

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0395

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

06/04/2010

10 DATE OF REVISION OF THE TEXT

23/02/2021