SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Strepsils Original Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Amylmetacresol	0.6mg
2,4-Dichlorobenzyl alcohol	1.2mg

Excipient(s) with known effect:
Carmoisine (E122)
Ponceau 4R (E124)
Liquid Glucose
Liquid Sucrose
Wheat Starch (containing gluten) *
Sulphites – sulphur Dioxide (E220)*
Anisyl Alcohol**
d-Limonene**
Linalool**
d-Limonene***
*present in Liquid Glucose
**present in Star Anise Oil
***present in Peppermint Oil

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

A red circular lozenge.

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 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

Hypersensitivity to any of the ingredients.

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, consult a doctor or health care professional.

Important information about some of the ingredients of this medicine:

This medicine contains 1.496 g sucrose per lozenge and 1.013 g glucose per lozenge. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-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 20.26 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 contains Carmoisine (E122) and Ponceau 4R (E124) which may cause allergic reactions.
This medicine contains sulphites – Sulphur dioxide (E220) which may rarely cause severe hypersensitivity reactions and bronchospasm.

This medicine contains fragrance with Anisyl Alcohol, d-Limonene and Linalool, which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interaction

No clinically significant interactions are 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

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

None available.

5.3 Preclinical safety data

None available.

6.1 List of excipients

Star anise oil (containing Anisyl Alcohol, d-Limonene and Linalool), peppermint oil (containing d-Limonene), menthol natural or menthol synthetic, tartaric acid gran 571 GDE, ponceau 4R edicol (E124), carmoisine edicol (E122), liquid glucose (containing wheat starch (containing gluten) and Sulphites – Sulphur Dioxide (E2220)), liquid sucrose, water (potable).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months for lozenges packed in blister strips within a carton.
24 months for blister packs attached to a stencilled card.

6.4 Special precautions for storage

Do not store above 25ºC.

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 or 90gms PVDC blister. The tray contains an appropriate number of lozenges to give pack sizes of 6, 8, 10, 12, 16, 20, 24, 32 and 36 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 or 90gms PVDC blister. Two, four or six blisters are attached to a stencilled card.
A blister push-through pack consisting of 15 or 20µm hard temper aluminium foil heat-sealed to a 250µm PVC/40gms or 90gms PVDC blister. The tray contains an appropriate number of lozenges to give a pack size of lozenges in a wrap around cardboard carton with tamper-evident seal.

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 00063/0396

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/03/2010

10 DATE OF REVISION OF THE TEXT

05/07/2022