SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Strepsils Extra Cherry Lozenges
Strepsils Extra Triple Action Cherry Lozenges
Strepsils Extra Strength Cherry Lozenges

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains Hexylresorcinol 2.4mg
Excipient(s) with known effect:
Glucose
Sucrose
Propylene Glycol (E1520)**
Citronellol and Geraniol**
Benzoic acid (E210) and benzoates**
Carmoisine (E122)
Sulphites- Sulphur Dioxide (E220)*
Wheat starch (containing Gluten)*

*present in liquid glucose
**present in cherry flavour

For excipients see Section 6.1

3 PHARMACEUTICAL FORM

Lozenge
A round red lozenge with the Strepsils brand icon entagliated on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

For oral administration.

Adults, the elderly and children 6 years and over: One lozenge dissolved slowly in the mouth every three hours or as required.

Do not take more than 12 lozenges in 24 hours.

Not to be given to children under 6 years.

4.3 Contraindications

Hypersensitivity to any of the ingredients

4.4 Special warnings and precautions for use

The label will convey:

Keep out of the reach and sight of children.

If symptoms persist consult your doctor.

Not to be given to children under 6 years.

Important information about some of the ingredients of 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 22.46 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 5.37 mg propylene glycol in each lozenge.
- This medicine contains Benzyl benzoate (present as part of cherry flavour) which may cause local irritation.
- This medicine contains fragrance with Citronellol and Geraniol. Citronellol and Geraniol may cause allergic reactions.
- This medicine contains Carmoisine (E122) which may cause allergic reactions.
- Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.
- This medicine contains Sulphites – Sulphur Dioxide present in liquid glucose which may rarely cause severe hypersensitivity reactions and bronchospasm.

4.5 Interaction with other medicinal products and other forms of interaction

None known

4.6 Pregnancy and lactation

There is lack of evidence of safety of the product in human pregnancy and in animals, but hexylresorcinol has been used widely in lozenges for many years without apparent ill consequence. However, as with all medicines, caution should be exercised during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Not known	Hypersensitivity[1]

[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

Hexylresorcinol overdosage may cause minor gastrointestinal irritation. Treatment would be withdrawal of the product and symptomatic measures as appropriate.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Hexylresorcinol is a local anaesthetic for topical use on the mucous membranes of the mouth and throat. Mild antiseptic activity has also been demonstrated.

The product base has a demulcent action.

5.2 Pharmacokinetic properties

Pharmacokinetic considerations do not arise since the pharmacological action is local to the oro-pharyngeal cavity.

5.3 Preclinical safety data

There are no preclinical data of relevance additional to those already included in other sections of the SPC.

6.1 List of excipients

Liquid sucrose, Liquid glucose (wheat starch (containing gluten), Sulphites – Sulphur Dioxide (E220)), Levomenthol, Cherry flavour (Propylene glycol (E1520), Benzoic acid (E210) and benzoates, citronellol and geraniol), Propylene glycol (E1520), Carmoisine edicol (E122)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

36 months for the unopened blister pack

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Blister packs of 250 micron PVC coated 40 gsm PVDC with 20 micron hard temper aluminium foil, heat sealed to the PVC/PVDC blister containing 6, 8, 10, 12, 16, 20, 24, 32, 36 or 48 lozenges in a carton.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

None specific to the product/pack

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Ltd
Slough
SL1 3UH

8 MARKETING AUTHORISATION NUMBER(S)

PL 00063/0393

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

20/04/2010

10 DATE OF REVISION OF THE TEXT

09/03/2021