SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Strepsils Orange with Vitamin C 100mg
Strepsils Dry & Sore Throat

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Amylmetacresol BP 0.6mg
2,4-Dichlorobenzyl Alcohol HSE 1.2mg
Vitamin C, (Ascorbic Acid, Sodium Ascorbate Equivalent to EP) 100.0mg

Excipient(s) with known effect:
Propylene Glycol
Fragrance containing allergens (Blood Orange Flavour – containing Citral, Citronellol, d-Limonene, Geraniol and Linalool)
Glucose (containing wheat starch (containing gluten), Sulphites- Sulphur Dioxide (E220))
Sucrose
Azo colouring agents – Ponceau 4R (E124) and Sunset Yellow (E110)

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Orange flavoured and coloured 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.

Children over 6 years old:
As above for adults.

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

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 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 19.36 micrograms of gluten.
If you have wheat allergy (different from coeliac disease) you should not take this medicine.
This medicine contains 3 mg propylene glycol in each Lozenge.
This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.
This medicine contains fragrance with Citral, Citronellol, d-Limonene, Geraniol and Linalool. Citral, Citronellol, d-Limonene, Geraniol and Linalool may cause allergic reactions.
This medicine contains glucose (0.97g per lozenge) and sucrose (1.44g 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 sucrose-isomaltose insufficiency should not take this medicine.

This medicine contains sulphites – Sulphur dioxide (E220) which may rarely cause severe hypersensitivity reactions and bronchospasm.
This medicine contains colouring agents (Ponceau 4R (E124) and Sunset Yellow (E110)), 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, 2,4-dichlorbenzyl alcohol and ascorbic acid.

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

Breast-feeding
Ascorbic acid or metabolites are excreted in human milk, but at therapeutic doses of the product no effects on breastfed newborns / infants are anticipated. 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.

Ascorbic acid provides a source of vitamin C, which may be beneficial during infection when vitamin C levels are believed to fall.

5.2 Pharmacokinetic properties

None stated.

5.3 Preclinical safety data

None available.

6.1 List of Excipients

Menthol natural or menthol synthetic
Tartaric acid
Blood Orange PHL 105288 (containing Citral, Citronellol, d-Limonene, Geraniol and Linalool)
Propylene glycol
Sunset yellow FCF (E110)
Ponceau 4R (E124) (containing Sodium)
Liquid Sucrose Liquid glucose BPC 1963 (containing wheat starch (containing gluten), Sulphites- Sulphur Dioxide (E220))

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

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

Do not store above 25°C.

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. 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.
A blister push-through pack consisting of hard temper aluminium foil heat-sealed to a PVC/PVDC blister. Two, four or six blisters are attached to a stencilled card.
A blister push-through pack consisting of hard temper aluminium foil heat-sealed to a PVC/PVDC blister. The tray contains an appropriate number of lozenges to give pack sizes of 8 lozenges in a wrap-round 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.

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 00063/0391

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/03/2010

10 DATE OF REVISION OF THE TEXT

21/04/2021