

SUMMARY OF PRODUCT CHARACTERISTICS

1. TRADE NAME OF THE MEDICINAL PRODUCT

Strepsils Orange with Vitamin C Lozenges
Amylmetacresol 0.6mg
2, 4-Dichlorobenzyl Alcohol 1.2mg
Vitamin C 100mg

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains 0.6 mg Amylmetacresol, 1.2 mg 2, 4-Dichlorobenzyl Alcohol and 100 mg Vitamin C (as Ascorbic Acid and Sodium Ascorbate).

Excipients with known effects:

Glucose 0.97 g (968 mg)/lozenge.

Sucrose 1.44 g (1438 mg)/lozenge.

Propylene glycol 3 mg/lozenge.

Wheat Starch (containing gluten present in liquid glucose) 19.36 micrograms/lozenge.

Sulphites - Sulphur Dioxide (E220) present in liquid glucose 0.124 ppm/lozenge.

Orange flavour fragrances containing citral, citronellol, d-Limonene, geraniol and linalool.

Colouring agents Ponceau 4R (E124) and Sunset yellow (E110).

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lozenge

An orange flavoured and coloured circular lozenge. Embossed on both sides with strepsils brand icon.

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of mouth and throat infection.

4.2 Posology and Method of Administration

Posology:

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms. It is recommended that the product should be used for a maximum of 3 days.

Adults: One lozenge every 2-3 hours. Do not take more than 12 lozenges in 24 hours.

Paediatric populations:

Children over 6 years of age: As above for adults.

Children under 6 years of age:

Not suitable for children under 6 years (see section 4.4)

Elderly:

There is no need for dosage reduction in the elderly.

Method of administration:

For oromucosal administration. To be dissolved slowly in the mouth.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltase insufficiency should not take this medicine.

4.4 Special Warnings and Special Precautions for Use

This product is not recommended for young children due to a risk of choking.

Consult your doctor if symptoms persist or if anything unusual happens.

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 less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'.

This medicine contains 0.97 g glucose and 1.44 g sucrose 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 sucrase-isomaltase insufficiency should not take this medicine.

This medicine contains 3 mg propylene glycol per lozenge.

Fragranced with citral, citronellol, d-Limonene, geraniol and linalool which may cause allergic reactions.

Also contains sulphites – Sulphur dioxide (E220) which may rarely cause severe hypersensitivity reactions and bronchospasm.

The colouring agents Sunset yellow (E110) and Ponceau 4R (E124) may cause allergic reactions.

4.5 Interactions

No clinically significant interactions are known.

4.6 **Pregnancy and Lactation**

Pregnancy

There are no or limited amount of data (less than 300 pregnancy outcomes) from the use of amylmetacresol, 2,4-dichlorobenzyl alcohol and ascorbic acid in pregnant women. As a precautionary measure, it is preferable to avoid the use of Strepsils during pregnancy.

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. There is insufficient information on the excretion of amylmetacresol or 2,4-dichlorobenzyl alcohol metabolites in human milk. A risk to the newborns/infants cannot be excluded.

Fertility

Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity.

4.7 **Effects on ability to Drive and Use Machines**

No adverse effects are known.

4.8 **Undesirable Effects**

The list of the following adverse effects relates to those experienced with 2,4-dichlorobenzyl alcohol, amylmetacresol and ascorbic acid at OTC doses, in short term use. In the treatment of chronic conditions, under long-term treatment, additional adverse effects may occur.

Adverse events which have been associated with 2,4-dichlorobenzyl alcohol, amylmetacresol and ascorbic acid are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common ($\geq 1/10$); Common ($\geq 1/100$ and $< 1/10$); Uncommon ($\geq 1/1000$ and $< 1/100$); Rare ($\geq 1/10,000$ 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 ¹
Gastrointestinal Disorders	Not known	Abdominal pain, nausea, oral discomfort ²
Skin and Subcutaneous Tissue Disorders	Not known	Rash

Description of Selected Adverse Reactions

¹ Hypersensitivity reactions may present in the form of rash, angioedema, urticaria, bronchospasms and hypotension with syncope.

² Oral discomfort may present in the form of throat irritation, oral paraesthesia, oedema of the mouth and glossodynia.

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 Pharmacovigilance Section, Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Centre, Earlsfort Terrace, Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie

4.9 Overdose

Symptoms:

Overdosage should not present a problem other than gastrointestinal discomfort.

Management:

Treatment should be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic Properties

Pharmacotherapeutic group: Throat Preparations; Antiseptics;

ATC Code: R02AA03 Dichlorobenzyl alcohol.

Mechanism of action

2,4-Dichlorobenzyl alcohol and amylmetacresol are antiseptics and possess antibacterial, antifungal and antiviral properties. Both AMC and DCBA also reversibly block depolarisation-induced ion channels in a similar way to local anaesthetics. When the two active agents are combined, a synergistic antibacterial action is observed leading to the reduced combined dose used in Strepsils lozenges.

Ascorbic acid and sodium ascorbate provide a source of Vitamin C, which may be beneficial during infection when Vitamin C levels are believed to fall.

Clinical efficacy and safety

Evidence of an analgesic effect for Strepsils in reducing throat soreness, providing pain relief and relief from difficulty in swallowing has been demonstrated to clinical studies with an onset in 5 minutes which lasts for up to 2 hours. Significantly more relief than nonmedical lozenge was also demonstrated for up to 3 days treatment.

Strepsils lozenge have also been shown to significantly decrease postoperative throat soreness and hoarseness 20 minutes and 24 hours after intubation.

A study in children (6-16 years) with acute and recurring chronic sore throat demonstrates a reduction in subjective and objective signs of sore throat over 3 days.

Strepsils Orange with Vitamin C lozenge base has a demulcent action providing throat soothing.

5.2 Pharmacokinetic Properties

None stated.

5.3 Preclinical Safety Data

Not applicable.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Levomenthol

Tartaric Acid

Flavour Blood Orange PHL 105288 (containing citral, citronellol, d-Limonene, geraniol and linalool)

Propylene glycol

Sunset yellow FCF (E110)

Ponceau 4R (E124)

Liquid Glucose

Liquid Sucrose

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years

6.4 Special Precautions for Storage

Do not store above 25°C

6.5 Nature and Contents of Containers

A clear blister push-through pack consisting of 15 or 20µm hard temper aluminium foil heat sealed to a 250µm or PVC/90gsm PVDC blister. Each blister tray contains 12 lozenges. Two trays are packed in a carton providing a pack size of 24 or 36 lozenges. 2 lozenge sample pack.

6.6 Instructions for Use and Handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd.,
7 Riverwalk,
Citywest Business Campus,
Dublin 24

8. MARKETING AUTHORISATION NUMBER

PA 979/39/1

9. DATE OF FIRST AUTHORISATION/RENEWAL OF AUTHORISATION

Date of first authorisation: 24th September 1985

Date of last renewal: 24th September 2010

10. DATE OF (PARTIAL) REVISION OF THE TEXT

July 2021