

PHYSICIAN'S PRESCRIBING INFORMATION

1. Name of the medicinal product

Strepsils Orange with Vitamin C 100mg

2. Qualitative and quantitative composition

Amylmetacresol 0.6mg

2,4-Dichlorobenzyl Alcohol 1.2mg

Vitamin C, (Ascorbic Acid, Sodium Ascorbate) 100.0mg

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

Antiseptic.

To relieve throat pain in children and adults.

4.2 Posology and method of administration

Posology

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

Adults and children above 6 years old:

One lozenge every 2-3 hours up to a maximum of 10 lozenges in 24 hours.

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.

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

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-dichlorobenzyl 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 ($\geq 1/10$); 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 ^{ab1}
Gastrointestinal Disorders	Not known	Glossodynia ^{ab} , oral discomfort ^{ab}

^a2,4-dichlorobenzyl alcohol ^bamylmetacresol

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form <https://sideeffects.health.gov.il/>

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. Pharmaceutical particulars

6.1 List of excipients

Liquid sucrose
Liquid glucose
Tartaric acid
Blood Orange PHL 105288
Propylene glycol
Levomenthol
Sunset yellow (E110)
Ponceau 4R (E124)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

A blister push-through pack consisting of hard temper aluminium foil heatsealed to a PVC/PVDC blister. The tray contains an appropriate number of lozenges to give pack sizes of 24 and 36 lozenges in a cardboard carton.

6.6 Special precautions for disposal and other handling

Not applicable.

7. Manufacturer

Reckitt Benckiser Healthcare Ltd.,
Nottingham NG90 2DB, UK

8. Registration holder

Reckitt Benckiser (Near East) Ltd. Hanagar 6, Hod Hasharon 4527704

9. Registration Number

066-33-25662-00

Revised on March 2021.