

PHYSICIAN'S PRESCRIBING INFORMATION

1 NAME OF THE MEDICINAL PRODUCT

Strepsils Strawberry Sugar Free
Strepsils Lemon Sugar Free

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains amylmetacresol 0.6 mg and 2, 4-Dichlorobenzyl alcohol 1.2 mg.

Excipients with known effects:

Strepsils Strawberry Sugar Free:

Propylene Glycol 7.30 mg/lozenge.
Isomalt 1.83 g /lozenge.
Maltitol liquid 0.458 g /lozenge.
Benzyl Alcohol (present in Strawberry flavour) 0.0028 mg/lozenge.

Strepsils Lemon Sugar Free:

Maltitol: 0.458 g /lozenge
Isomalt: 1.83 g /lozenge
Fragrance containing allergens – benzyl alcohol, citral, citronellol, dlimonene, geraniol and linalool (in the Lemon flavour)

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Strepsils Strawberry Sugar Free: Lozenge, Pink, circular lozenge with a characteristic strawberry taste, embossed on both sides with strepsils brand icon.

Strepsils Lemon Sugar Free: A white to pale yellow, circular lozenge with a characteristic lemon taste and the Strepsils brand icon intagliated on both sides.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Strepsils Sugar Free lozenges are indicated for the relief of sore throat in adults and children.

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 population:

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

Strepsils Sugar Free Strawberry and Lemon are contraindicated in persons who have previously shown hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

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

This medicine also contains 1.83 g isomalt and 0.458 g maltitol liquid. Patients with rare hereditary problems of fructose intolerance should not take this medicine. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product. May have a mild laxative effect. Calorific value 2.3 kcal/g.

Strepsils Strawberry Sugar Free

This medicine contains 7.30 mg propylene glycol (present in strawberry flavour) in each lozenge.

This medicine contains benzyl alcohol in each lozenge which may cause allergic reactions.

Strepsils Lemon Sugar Free

This medicine contains fragrance with Benzyl Alcohol, Citral, Citronellol, d-Limonene, Geraniol and Linalool which may cause allergic reactions.

4.5 Interaction with other medicinal products and other forms of interactions

Not applicable.

4.6 Fertility, pregnancy and lactation

Pregnancy

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

Breast-feeding

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 and amylmetacresol 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 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	Frequen	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. 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

Symptoms:

In view of the nature and presentation of Strepsils Sugar Free Lozenges, accidental or deliberate overdosage is highly unlikely. 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.

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 Sugar Free lozenges base have a demulcent action providing throat soothing.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Strepsils Strawberry Sugar Free

Strawberry Flavour 052312B (contains benzylalcohol)
Pink Antho (E163)
Sodium Saccharin
Tartaric Acid
Isomalt
Maltitol Syrup

Strepsils Lemon Sugar Free

Lemon flavour (fragrance containing allergens – benzyl alcohol, citral, citronellol, dlimonene, geraniol and linalool)
Saccharin sodium
Tartaric acid
Isomalt (Isomaltitol)
Maltitol liquid

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Strepsils Strawberry Sugar Free: 2 years

Strepsils Lemon Sugar Free: 3 years

6.4 Special precautions for storage

Do not store above 25°C

6.5 Nature and contents of container

Strepsils Strawberry Sugar Free lozenges are packed in blisters made up of white (opaque) 250 micron Polyvinyl Chloride (PVC), coated with 90 g/m² Polyvinylidene Chloride (PVDC).

The blisters are heat sealed to 20 microns Aluminium lidding material coated with 7 g/m² of heat sealing lacquer.

Strepsils Lemon Sugar Free lozenges are packed in blisters made up of Clear 250 micron Polyvinyl Chloride (PVC), coated with 40 or 90 g/m² Polyvinylidene Chloride (PVDC).

The blisters are heat sealed to 20 microns Aluminium lidding material coated with 7 g/m² of heat sealing lacquer.

Each blister contains 6, 8, 12, 16, 18, 20, 24, 32 or 36 lozenges

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

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

Strepsils Strawberry Sugar Free: 112-45-29476-00

Strepsils Lemon Sugar Free: 052-52-24917-00

10 DATE OF REVISION OF THE TEXT

Revised in April 2023.