

PHYSICIAN'S PRESCRIBING INFORMATION

1. Name of the medicinal products

Strepsils Honey and Lemon
Strepsils Menthol & Eucalyptus

2. Qualitative and quantitative composition

- Amylmetacresol 0.6mg
- 2,4-Dichlorobenzyl Alcohol 1.2mg
- Menthol 8mg (Strepsils Menthol & Eucalyptus)

Excipient(s) with known effect;

Strepsils Honey and Lemon

- Glucose (containing Sulphites – Sulphur Dioxide (E220) and Wheat Starch (containing gluten))
- Sucrose
- Invert Sugar (Honey)
- Fragrance containing allergens - Citral, d-Limonene*, Geraniol and Linalool (present in Terpeneless lemon oil)

* present also in Peppermint oil

Strepsils Menthol & Eucalyptus

- Liquid Glucose (containing Wheat Starch (containing Gluten) and Sulphites – Sulphur Dioxide (E220))
- Liquid Sucrose
- D-Limonene (present in Eucalyptus oil)

For a full list of excipients, see section 6.1.

3. Pharmaceutical form

Strepsils Honey and Lemon : A yellow circular lozenge.

Strepsils Menthol & Eucalyptus : A blue circular lozenge with a characteristic taste.

4. Clinical particulars

4.1 Therapeutic indications

Antiseptic for the relief of sore throat 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 12 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.

Important information about some of the ingredients of this medicine:

- **Strepsils Honey and Lemon** contains sucrose (1.44g per lozenge) and glucose (0.98g per lozenge). **Strepsils Menthol & Eucalyptus** (1.497g per lozenge) and glucose (1.013g 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.
- These medicines contain 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 19.52 micrograms of gluten (Strepsils Honey and Lemon) & no more than 20.26 micrograms of gluten (Strepsils Menthol & Eucalyptus). If you have wheat allergy (different from coeliac disease) you should not take these medicines.
- These medicines contain less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.
- These medicines contain Sulphites – Sulphur Dioxide (E220) (present in liquid glucose) which may rarely cause severe hypersensitivity reactions and bronchospasm.
- Strepsils Honey and Lemon: This medicine contains fragrance with Citral, d-Limonene, Geraniol and Linalool. Citral, d-Limonene, Geraniol and Linalool may cause allergic reactions.
- Strepsils Menthol & Eucalyptus: This medicine contains fragrance with d-Limonene (Eucalyptus oil), d-limonene 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-dichlorobenzyl alcohol and Levomenthol (Strepsils Menthol & Eucalyptus).

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

Breast-feeding

It is unknown whether 2,4-dichlorobenzyl alcohol, amylmetacresol, Levomenthol (Strepsils Menthol & Eucalyptus) 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 are antiseptics and possess antibacterial (bactericidal and bacteriostatic), antifungal and antiviral properties as demonstrated *in vitro*. When the two active agents are combined, a synergistic antibacterial action is observed leading to a reduced combined dose.

In-vitro studies demonstrated killing effects against some sore throat causing organisms such as *Streptococcus pyogenes*, *Staphylococcus aureus*, *Haemophilus influenza* and *Moraxella catarrhalis*, at 1 minute contact time. An overall reduction in the oral bacterial load was also seen in one *in-vivo* study.

In-vitro antiviral action against enveloped viruses including influenza A virus, para-influenza virus, respiratory syncytial virus, cytomegalovirus and coronavirus has also been observed for both AMC and DCBA as well as the combination of the two after 1-2 minutes contact.

In clinical studies, there was evidence that Strepsils lozenges led to reduction of throat soreness, and provided relief from pain and difficulty in swallowing, with onset of activity in 5 minutes and lasting for up to 2 hours. Significantly more relief than non-medicated lozenge was also demonstrated for up to 3 days treatment. In one study, Strepsils lozenges have also been shown to significantly decrease post-operative 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 demonstrated a reduction in subjective and objective signs of sore throat over 3 days of treatment with Strepsils lozenges.

Strepsils Honey & Lemon lozenges contain flavours and honey whilst the base has a demulcent action providing throat soothing.

Strepsils Menthol & Eucalyptus contains Menthol. Menthol has a mild local anaesthetic action on the throat and also relieves the symptoms of cough and nasal congestion.

5.2 Pharmacokinetic properties

None available.

5.3 Preclinical safety data

None available.

6. Pharmaceutical particulars

6.1 List of excipients

Strepsils Honey & Lemon

Liquid sucrose, Liquid glucose (containing sulphites – Sulphur Dioxide (E220) and wheat starch (containing gluten), Honey, Tartaric acid, Peppermint oil (containing d-

Limonene), Terpeneless lemon oil (containing Fragrance containing allergens - Citral, d-Limonene, Geraniol and Linalool), Quinoline yellow.

Strepsils Menthol & Eucalyptus

Liquid sucrose, Liquid glucose (containing sulphites – Sulphur Dioxide (E220) and wheat starch (containing gluten), Tartaric acid, Eucalyptus oil (containing d-Limonene), Indigo carmine.

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

Strepsils Honey and Lemon 049-56-24205-00
Strepsils Menthol & Eucalyptus 053-50-26858-00

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