STREPSILS SOOTHING HONEY AND LEMON LOZENGES – SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Strepsils Soothing Honey and Lemon Lozenges

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Amylmetacresol 0.6mg

2,4-Dichlorobenzyl alcohol 1.2mg

Excipient(s) with known effect;

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

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A yellow 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.

Elderly:

There is no need for dosage reduction in the elderly.

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:

This medicine contains sucrose (1.44g per lozenge) and glucose (0.98g 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 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.

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 fragrance with Citral, d-Limonene, Geraniol and Linalool.

Citral, d-Limonene, Geraniol and Linalool may cause allergic reactions.

This medicine contains Sulphites - Sulphur Dioxide (E220) (present in liquid glucose) which may rarely cause severe hypersensitivity reactions and bronchospasm.

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 and 2,4-dichlorbenzyl alcohol.

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 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 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.

5.2 Pharmacokinetic properties

None available.

5.3 Preclinical safety data

None available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Honey, tartaric acid, peppermint oil (containing d-Limonene), terpeneless lemon oil (containing Fragrance containing allergens - Citral, d-Limonene, Geraniol and Linalool), quinoline yellow, liquid sucrose, liquid glucose (containing sulphites - Sulphur Dioxide (E220) and wheat starch (containing gluten)), potable water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months for lozenges packed in blister strips within a carton.

36 months for lozenges packed in polypropylene tube, with an in use shelf-life of 'use within 3 months of opening'.

18 months for blister packs attached to a stencilled card.

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 4**,** 6, 8, 10, 12, 16, 20, 24, 32, 36 and 48 lozenges in cardboard cartons or a flow wrap outer composed of PET/aluminium foil/polyethylene

Sample packs consisting of two, four or six individual lozenge blister strips attached to a 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 a pack size of 8 lozenges in a wrap around 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.

20 lozenges consisting of a bundled pack of 2 tubes of 10 lozenges each.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Not applicable.

7. MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Healthcare (UK) Ltd

Slough

SL1 3UH

8. MARKETING AUTHORISATION NUMBER(S)

04-2087

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

19/03/2010

10. DATE OF REVISION OF THE TEXT

04/03/2021