SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Strepsils Pain Relief Plus.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients	Quantity	Specification
Amylmetacresol	0.6mg	BP
2,4-Dichlorobenzyl alcohol	1.2mg	HSE
Lidocaine hydrochloride	10.0mg	Ph Eur
(Lidocaine base	8.11mg)	Ph Eur

An overage of 2.5% is added for amylmetacresol, 5.0% for 2,4-Dichlorobenzyl alcohol and 4% for Lidocaine hydrochloride.

Also contains the following excipients:

Liquid Glucose (which contains Wheat Starch and Sulphur Dioxide)

Liquid Sucrose

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Pale blue-green circular, translucent lozenge with an icon intagliated on both sides of the lozenge. The lozenge has a mint taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Strepsils Pain Relief Plus lozenges are indicated for the symptomatic relief of mouth and throat infections including severe sore throat.

Strepsils Pain Relief Plus is indicated in adults, children and adolescents aged 12 to 18 years of age.

4.2 Posology and method of administration

Posology

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

Adults

One lozenge every two hours as required. No more than 8 to be sucked in any 24 hours.

Paediatric population

Children over 12 years

As above for adults.

Children under 12 years

Not recommended for children under 12 years (see section 4.3).

Elderly

There is no need for dosage reduction in the elderly.

Method of administration

For oral administration. To be sucked slowly.

4.3 Contraindications

Strepsils Pain Relief Plus lozenges are contraindicated in persons who have previously shown hypersensitivity to any of the active ingredients or to any of the excipients listed in section 6.1.

A history of allergy to local anaesthetics of the amide-type.

In patients who have a history of or are suspected to have methaemoglobinaemia.

Patients suffering from asthma or bronchospasm.

Children under 12 years of age.

4.4 Special warnings and precautions for use

Consult your doctor if symptoms persist after 3 days, or are accompanied by a high fever or headache.

Consult your doctor before taking this product if you are pregnant or breast-feeding.

Important information about some of the ingredients of this medicine:

This medicine contains glucose and sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galalctose malabsorption or sucrose-isomaltase 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 19.60 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 sulphites – Sulphur dioxide (E220) which may rarely cause severe hypersensitivity reactions and bronchospasm.
This medicine contains fragrance with Anisyl Alcohol, d-Limonene and Linalool, which may cause allergic reactions

4.5 Interaction with other medicinal products and other forms of interaction

While a number of interactions are theoretically possible with lidocaine, these drug interactions are unlikely to become clinically significant to the safety of the patients as the product is administered topically.

The toxicity of oral lidocaine may be increased when the drug is taken in combination with the following drugs:

- Erythromycin
- Itraconazole
- Cimetidine
- Fluvoxamine
- Beta blockers
- Other antiarrhythmic drugs (e.g. Mexiletine)

4.6 Fertility, pregnancy and lactation

Pregnancy

The safety of this medicinal product for use in human pregnancy has not been established. However, a moderate amount of data on pregnant women (between 300-1000 pregnancy outcomes) indicate no malformative or feto/ neonatal toxicity of lidocaine. There are no or limited amount of data from the use of amylmetacresol and 2,4-dichlorobenzyl alcohol.

The product is therefore not recommended during pregnancy except under medical supervision.

Breast-feeding

Lidocaine/ metabolites are excreted in human milk, but at therapeutic doses of the product no effects on the breastfed newborns/ infants are anticipated. It is unknown whether

amylmetacresol, 2,4-dichlorobenzyl alcohol or metabolites are excreted in human milk. A risk to newborns / infants cannot be excluded.

The product is therefore not recommended during lactation except under medical supervision.

Fertility

No data are available regarding the effects of the active substances on fertility.

4.7 Effects on ability to drive and use machines

No adverse effects are known.

4.8 Undesirable effects

Adverse events which have been associated with amylmetacresol, 2,4-dichlorobenzyl alcohol and lidocaine 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
Blood and Lymphatic System Disorders	Not Known	Methaemoglobinaemia
Immune System Disorders	Not known	Hypersensitivity[1]
Gastrointestinal Disorders	Not known	Abdominal pain, nausea, oral discomfort
Skin and Subcutaneous Tissue Disorders	Not known	Rash

Description of Selected Adverse Reactions

1 Hypersensitivity reactions to lidocaine may present in the form of angioedema, urticarial, bronchospasms and hypotension with syncope.

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 reaction 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 will initially only produce excessive anaesthesia of the upper alimentary tract. However lidocaine intoxication can result in severe hypotension, asystole, bradycardia, apnoea, seizures, coma, cardiac arrest, respiratory arrest and death.

In view of the nature and presentation of Strepsils Pain Relief Plus lozenges, accidental or deliberate overdosage is highly unlikely.

Treatment of potentially toxicological overdose should be symptomatic and supportive and conducted under medical supervision.

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. Lidocaine is a local anaesthetic of the amide type, acting to produce reversible loss of sensation by preventing or diminishing the generation and transmission of sensory nerve impulses near the site of application. Depolarisation of the neuronal membrane and ion exchange are reversibly inhibited. It provides an anaesthetic effect by blocking neuronal transmission.

5.2 Pharmacokinetic properties

Lidocaine is readily absorbed from mucous membranes. The plasma elimination half life is about 2 hours.

Lidocaine undergoes significant first pass metabolism in the liver and is rapidly de-ethylated to the active metabolites including glycinexylidide. Less than 10% is excreted unchanged by the kidneys. The metabolites are also excreted in the urine.

2,4-Dichlorobenzyl alcohol is metabolised by the liver to form hippuric acid which is excreted in the urine.

No data available on amylmetacresol metabolism and elimination.

5.3 Preclinical safety data

There are no preclinical safety data of relevance to the consumer.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tartaric acid

Sodium saccharin

Levomenthol

Peppermint oil

Star Anise oil

Quinoline yellow (E104)

Indigo carmine (E132)

Liquid sugar for confectionery

Liquid glucose

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

The lozenges are contained in a strip pack. The tray contains an appropriate number of lozenges to give pack sizes of 24, 32 and 36 lozenges in a cardboard carton.

6.6 Special precautions for disposal

Not applicable.

7 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser healthcare (UK) limited
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Slough
Berkshire
SL1 3UH
United Kingdom

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PL 00063/0427

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10 DATE OF REVISION OF THE TEXT

21/04/2020