Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Strepsils +Plus Anaesthetic Lozenges
Amylmetacresol 0.6mg
2,4-Dichlorobenzyl Alcohol 1.2mg
Lidocaine Hydrochloride 10mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains 0.6 mg Amylmetacresol, 1.2 mg 2, 4-Dichlorobenzyl Alcohol and 10 mg Lidocaine Hydrochloride.

Excipients with known effects:
Glucose 0.98 g (980 mg)/lozenge.
Sucrose 1.52 g (1523 mg)/lozenge.
Wheat Starch (containing gluten) 19.60 µg/lozenge present in liquid glucose.
Sulphites - Sulphur Dioxide (E220) 0.125 ppm/lozenge present in liquid glucose.
Star Anise oil contains Anisyl alcohol, d-limonene and linalool.
Peppermint oil contains d-Limonene.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Lozenge

Pale, blue-green circular lozenges, embossed on both sides with Strepsils brand icon.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Strepsils +Plus anaesthetic Lozenges are indicated for the symptomatic relief of mouth and throat infections including severe sore throat.

Strepsils +Plus Anaesthetic Lozenges is indicated in adults and children over 12 years of age.

4.2 Posology and method of administration

Posology

The lowest effective dose should be used for the shortest duration necessary to relieve symptoms.

Adults
One lozenge to be sucked slowly every two hours as required. No more than 8 lozenges 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 4.4)

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 +Plus anaesthetic 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 anesthetics of the amide type.
In patients who have a history of or are suspected to have methaemoglobinaemia.

4.4 Special warnings and precautions for use

Not recommended for children under 12 years.

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 0.98 g glucose and 1.52 g sucrose 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 sucrase-insomaltase insufficiency should not take this medicine.

This medicine contains fragrance with Anisyl alcohol, d-Limonene and linalool which may cause allergic reactions.

Also contains sulphites – Sulphur Dioxide (E220) which rarely cause severe hypersensitivity reactions and bronchospasm.

Warning: Do not exceed the stated dose.
Keep all medicines out of the reach of children.
Consult your doctor within 3 days if symptoms persist or are accompanied by high fever or headache, or if anything unusual happens.
Consult your doctor before taking this product if you are pregnant or breast feeding.
Consult your doctor if you suffer from asthma or bronchospasm.

This product may cause numbness of the tongue and therefore care should be taken in eating and drinking after taking the lozenge.

4.5 Interaction with other medicinal products and other forms of interactions

While a number of interactions are theoretically possible with lidocaine, these drug interactions are unlikely to be clinically relevant to the safety of the patient 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:

- CYP34A inhibitor drugs (e.g. erythromycin, itraconazole and ketoconazole)
- CYP1A2 inhibitor drugs (e.g. fluvoxamine and cimetidine)
- 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. 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 the therapeutic doses of the product no effects on the breastfed newborns/infant are anticipated. There is insufficient information on the excretion of amylmetacresol or 2,4-dichlorobenzyl alcohol metabolites 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
Immune System Disorders	Not known	Hypersensitivity[1]
Gastrointestinal Disorders	Not known	Nausea, oral discomfort
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.

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 HPRA Pharmacovigilance. Website: www.hpra.ie.

4.9 Overdose

In view of the nature and presentation of Strepsils +Plus Anaesthetic Lozenges, accidental or deliberate overdosage is unlikely.

Symptoms
Overdosage will initially produce excessive anaesthesia of the upper alimentary tract and should not present a problem other than gastrointestinal discomfort. The most serious effects of lidocaine intoxication are on the central nervous system and cardiovascular system and may also include methaemoglobinaemia, severe hypotension, asystole, bradycardia, apnoea, seizures, coma, cardiac arrest, respiratory arrest and death.

Management
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; R02AA03 Dichlorobenzyl alcohol

2,4-Dichlorobenzyl Alcohol and Amylmetacresol have antiseptic properties. Lignocaine 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

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

Lignocaine undergoes significant first pass metabolism in the liver and is rapidly de-ethylated to the active metabolite and then hydrolysed to various 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 metabolized 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

The LD_{50} for 2,4-dichlorobenzyl alcohol in rats has been determined as 3g per kg bodyweight. Based on this data, the NOAEL (no-observed-adverse-effect level) for 2,4-dichlorobenzyl alcohol has been identified at a daily dose of 100mg per kg of bodyweight in humans.

Animal studies indicate no negative effects of AMC, DCBA or lidocaine on the course of pregnancy or on foetal development at the recommended dose.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tartaric acid
Sodium saccharin
Levomenthol
Peppermint oil (d-limonene)
Star Anise oil (anisyl alcohol, d-limonene and linalool)
Quinoline yellow (E104)
Indigo carmine (E132)
Liquid sucrose
Liquid glucose (wheat starch & sulphur dioxide (E220))

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25ºC.

6.5 Nature and contents of container

The lozenges are contained in an AL/PVC/PVDC blister strip pack.
Pack size: 24 lozenges in two blister strips (2 x 12) in a cardboard carton.

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 MARKETING AUTHORISATION HOLDER

Reckitt Benckiser Ireland Ltd
7 Riverwalk
Citywest Business Campus
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER

PA0979/040/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 03 October 1995

Date of last renewal: 03 October 2010

10 DATE OF REVISION OF THE TEXT

March 2022