Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Strepsils +Plus Anaesthetic Throat Spray
Amylmetacresol 0.29mg/spray
2,4-Dichlorobenzyl Alcohol 0.58mg/spray
Lidocaine 0.78mg/spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Strepsils +Plus anaesthetic Throat Spray contains the following active substances:

Amylmetacresol	0.223 % w/v (0.580mg/dose)
2,4-Dichlorobenzyl alcohol	0.446 % w/v (1.16mg/dose)
Lidocaine	0.6 % w/v (1.56mg/dose)

There are two sprays per dose (each spray is 0.13ml) and each dose is 0.26 ml.

Excipients with known effects:

Ethanol (96%)	40.0% v/v (83.2mg/dose)
Sorbitol	10% v/v (33.6mg/dose)
Carmoisine Edicol (E122)	0.006% (33.6mg/dose)

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Oromucosal spray
Clear, pink liquid.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of throat infections, including severe sore throats.

4.2 Posology and method of administration

Posology

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

Adults: Two sprays, if necessary, repeat the dose every two hours as needed up to a maximum of eight times in 24 hours. Do not exceed the stated dose.

Paediatric Population

Not recommended for children.

Elderly Population

There is no need for dosage modifications in the elderly.

Method of administration

Oromucosal use. The nozzle should be aimed at the back of the throat and the product sprayed on to the affected area.

4.3 Contraindications

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.

4.4 Special warnings and precautions for use

Not recommended for children.
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 if anything unusual happens.
Consult your doctor if you suffer from asthma or bronchospasm.
Asthmatics should consult their doctor before first using this product.

Patients should not inhale whilst using the spray.

Excessive dosage, short intervals between doses or exposure onto traumatised mucosa may result in unnecessary systemic exposure. Care should be exercised.

This medicine contains 83.2 mg of alcohol (ethanol) in each dose. The amount in each dose of this medicine is equivalent to less than 2 ml beer or 1 ml wine. The small amount of alcohol in this medicine will not have any noticeable effects.

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium free'.

This medicine contains 33.6 mg sorbitol per dose.

Also contains Carmoisine Edicol (E122) colouring agent which may cause allergic reactions.

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 Strepsils +Plus anaesthetic Throat Spray for use in human pregnancy and lactation has not yet 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. 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. Therefore the product is 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

Symptoms

Overdosage of the product, which contains a low dose of lidocaine, should not present a problem other than gastrointestinal discomfort. However lidocaine intoxication can result in severe hypotension, asystole, bradycardia, apnoea, seizures, coma, cardiac arrest, respiratory arrest and death.

Management

In view of the nature of the container, it is believed that overdosage would not be a problem. In the unlikely event of overdose with this product, treatment should be symptomatic and supportive.

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. Lignocaine is a local anaesthetic of the amide type. It acts 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 significantly first-pass metabolism in the liver and is rapidly de-ethylated to the active metabolite monoethylglycine-xylidide 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 metabolised by the liver to form hippuric acid which is excreted in the urine.

No data are available for 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

Ethanol (96 per cent)
Citric acid monohydrate
Glycerol (E422)
Liquid sorbitol (non-crystallising) (E420)
Saccharin
Levomenthol
Peppermint flavour
Aniseed flavour
Carmoisine Edicol (E122)
Purified water
Sodium hydroxide (for pH-adjustment)
Concentrated hydrochloric acid (for pH-adjustment)

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

A clear glass bottle fitted with a polyethylene spray pump and nozzle containing 20 ml of product packed in a 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

PA0979/040/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

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Date of last renewal: 25 July 2006

10 DATE OF REVISION OF THE TEXT

March 2022