Applicant: Reckitt Benckiser Pharmaceuticals (Pty) Ltd
Product: Strepsils Eucalyptus Menthol
Dosage: Lozenges
Strength: 2, 4 Dichlorobenzyl Alcohol 1, 2 mg, Amylmetacresol 0, 6 mg, Levomenthol 8,0 mg

1.3.1.1 PROFESSIONAL INFORMATION

SCHEDULING STATUS:

Schedule 0

PROPRIETARY NAME AND (DOSAGE FORM):

STREPSILS EUCALYPTUS MENTHOL (LOZENGE)

COMPOSITION

Each lozenge contains:

2, 4 Dichlorobenzyl Alcohol	1,2 mg
Amylmetacresol	0,6 mg
Levomenthol	8,0 mg

Other ingredients include:

Eucalyptus oil, Indigo carmine, liquid sucrose, liquid glucose & tartaric acid.

Contains sugar (sucrose & glucose) 2,5 g

PHARMACOLOGICAL CLASSIFICATION:

A 16.4 Naso-pharyngeal and bucco-pharyngeal antiseptics

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties

Strepsils lozenges has antiseptic properties

Pharmacokinetic properties

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

No data is available for amylmetacresol metabolism and elimination.

Levomenthol is rapidly absorbed and metabolised into levomenthol glucuronide which is excreted in urine and faeces within 48 hours of ingestion

INDICATIONS:

Relief of sore throat.

1.3.1.1 PROFESSIONAL INFORMATION

CONTRA-INDICATIONS:

Hypersensitivity to any of the ingredients

Children under 6 years of age.

WARNINGS AND SPECIAL PRECAUTIONS:

Menthol may give rise to hypersensitivity reactions including contact dermatitis.

If the symptoms have not improved, or have worsened within 3 days, consult a doctor or health care professional.

Remember young children can choke on lozenges.

Effects on ability to drive and use machines

None reported.

Contains sucrose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose mal-adsorptions, sucrose-isomaltase insufficiency or diabetic patients should not take Strepsils Eucalyptus Menthol Lozenges.

INTERACTIONS:

No known interactions.

HUMAN REPRODUCTION

Safety has not been demonstrated in pregnancy and lactation.

DOSAGE AND DIRECTIONS FOR USE

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

Adults and children over 6 years of age:

Dissolve one lozenge slowly in the mouth every 2 to 3 hours.

Do not exceed 12 lozenges in any 24 hour period.

This product is contraindicated in children under 6 years of age.

1.3.1.1 PROFESSIONAL INFORMATION

SIDE EFFECTS

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Not known	Hypersensitivity
Gastrointestinal Disorders	Not known	Abdominal, pain nausea, oral discomfort
Skin and Subcutaneous Tissue Disorders	Not known	Rash, contact dermatitis

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

In the unlikely event of an overdose, serious side effects are not expected.

Some gastrointestinal discomfort may be experienced.

Treatment should be symptomatic.

IDENTIFICATION:

A blue, circular lozenge with a characteristic taste and Strepsils brand icon intagliated on both sides.

PRESENTATION:

Cartons containing 2, 4, 6, 8 or 24 blister packed lozenges.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

KEEP OUT OF THE REACH OF CHILDREN.

REGISTRATION NUMBER:

W/16.4/195

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Reckitt Benckiser Pharmaceuticals (Pty) Ltd

8 Jet Park Road

1.3.1.1 **PROFESSIONAL INFORMATION**

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DATE OF PUBLICATION OF THE PACKAGE INSERT:

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