

Date amended: 30 July 2012 (inclusion of sugar content)  
Date approved: 30/08/2012

1C.1.1

#### PROPOSED PACKAGE INSERT

##### **SCHEDULING STATUS:**

Schedule 0

##### **PROPRIETARY NAME (and dosage form):**

#### **STREPSILS ORANGE WITH VITAMIN C**

Lozenges

##### **COMPOSITION:**

Each lozenge contains:

Vitamin C	100,00 mg
2,4-Dichlorobenzyl Alcohol	1,20 mg
Amylmetacresol	0,60 mg
Sugar ( <i>sucrose and glucose</i> )	2.5 g

##### **PHARMACOLOGICAL CLASSIFICATION:**

A.16.4 Naso-pharyngeal and bucco-pharyngeal antiseptics.

##### **PHARMACOLOGICAL ACTION:**

Strepsils lozenges have disinfectant and antibacterial properties.

##### **INDICATIONS:**

Indicated for the relief of dry, irritated sore throat and coughs due to colds and allergies.

##### **CONTRA-INDICATIONS:**

There are no known contra-indications.

##### **DOSAGE AND DIRECTIONS FOR USE:**

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

Strepsils lozenges are suitable for adults and children.

##### **SIDE EFFECTS AND SPECIAL PRECAUTIONS:**

Menthol may give rise to hypersensitivity reactions including contact dermatitis.

Remember young children can choke on lozenges.

##### **Precautions:**

When a sore throat persists for more than two days, consult your doctor. Ascorbic Acid should be given with care to patients with hyperoxaluria.

##### **KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

Large doses of Vitamin C may cause diarrhoea and the formation of renal calcium oxalate calculi.

Doses of 600 mg or more daily have a diuretic action.

##### **IDENTIFICATION:**

An orange, circular lozenge with a characteristic orange and menthol taste and the Strepsils brand icon intagliated on both sides

##### **PRESENTATION:**

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

Printed aluminium foil sachets containing 2 lozenges.

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**STORAGE INSTRUCTIONS:**  
KEEP OUT OF REACH OF CHILDREN  
Store below 25°C

**REGISTRATION NUMBER:**  
S/16.4/144

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

Reckitt Benckiser Pharmaceuticals (Pty) Limited

8 Jet Park Road

Elandsfontein

1601

**DATE OF PUBLICATION OF THIS PACKAGE INSERT:**  
December 1991