

<b>Registration number</b>	45/16.4/0620
<b>Product Proprietary name</b>	Strepsils Warm Ginger
<b>Dosage strength</b>	Each lozenge contains: 2.4 Dichlorobenzyl alcohol 1,2 mg Amylmetacresol
<b>Applicant</b>	Reckitt Benckiser Pharmaceuticals (Pty) Ltd.
<b>Date</b>	April 2025

## Proposed Clean Professional Information

### SCHEDULING STATUS

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### 1 NAME OF THE MEDICINE

Strepsils Warm Ginger Lozenge

### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains:

2,4 Dichlorobenzyl alcohol	1,2 mg
Amylmetacresol	0,6 mg
Sugar (Sucrose and glucose)	2,5 g

For full list of excipients, see **section 6.1**

### 3 PHARMACEUTICAL FORM

A red to purple-coloured circular lozenge with characteristic taste of warm plum and ginger. Strepsils brand icon is intagliated on both sides.

### 4 CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

For the symptomatic relief of minor mouth and throat infections including sore throat.

#### 4.2 Posology and method of administration

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### **Posology**

Adults and children (over 6 years old): (see section 4.4)

One lozenge to be dissolved slowly in the mouth every 2-3 hours up to a maximum of 12 lozenges in 24 hours.

**Elderly:** There is no need for dosage reduction in elderly

### **Method of administration**

For oral administration

### **4.3 Contraindications**

Hypersensitivity to any of the ingredients of Strepsils Warm Ginger

Children under 6 years of age

### **4.4 Special warnings and precautions for use**

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltose insufficiency should not take this medicine.

As young children may choke on lozenges, Strepsils Warm Ginger is not indicated for children under the age of 6 years.

Caution should be taken when using Strepsils Warm Ginger in diabetic patients as Strepsils Warm Ginger contains Sugar Sucrose and glucose.

If symptoms persist for more than two days, consult a doctor.

### **4.5 Interaction with other medicines and other forms of interaction**

No clinically significant interactions are known.

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#### **4.6 Fertility, pregnancy, and lactation**

The safety in pregnancy and lactation has not been established.

##### **Pregnancy**

There are no or limited amount of data from the use of amylmetacresol and 2,4-dichlorobenzyl alcohol.

As with all medicines care should be taken when using this product in pregnancy and medical advice sought if necessary.

##### **Breast-feeding**

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

##### **Fertility**

No data are available regarding the effects on fertility.

#### **4.7 Effects on ability to drive and use machines**

Effects on ability to drive and use machines are not known.

#### **4.8 Undesirable effects**

The list of the following adverse effects relates to those experienced with 2,4-dichlorobenzyl alcohol and amylmetacresol at OTC doses, in short term use.

Adverse events which have been associated with 2,4-dichlorobenzyl alcohol and amylmetacresol are given below, tabulated by system organ class and frequency. Frequencies are defined as: Very common ( $\geq 1/10$ ); Common ( $\geq 1/100$  and  $< 1/10$ ); Uncommon ( $\geq 1/1000$  and  $< 1/100$ ); Rare ( $\geq 1/10,000$  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.

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<b>System Organ Class</b>	<b>Frequency</b>	<b>Adverse Events</b>
Immune System disorders	Less Frequent	Hypersensitivity <sup>1</sup>
Gastrointestinal Disorders	Not known	Glossodynia, oral discomfort

<sup>1</sup>Hypersensitivity reactions may include rash, urticaria and angioedema, which may include swelling of the face, neck, throat or tongue that could affect breathing

### **Reporting of suspected adverse reactions**

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

### **4.9 Overdosage**

Overdosage may cause hypersensitivity reaction and gastrointestinal discomfort, see **section 4.8**.

Treatment should be symptomatic and supportive.

## **5 PHARMACOLOGICAL PROPERTIES**

### **5.1 Pharmacodynamic properties**

**Pharmacological classification:** 16.4 Naso-pharyngeal and bucco-pharyngeal antiseptics

Strepsils lozenges have antiseptic properties.

### **5.2 Pharmacokinetic properties**

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Pharmacokinetically the active ingredients, when present in a dosage form such as a lozenge, will exert their desired effect locally on the oropharynx.

### **5.3 Preclinical safety data**

Not data

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Anthocyanins (E163)

Fruity plum flavor

Soothing cream flavor

Warm sensation flavor

Warm ginger spice flavor

Medium chain triglycerides

Tartaric acid and purified water.

### **6.2 Incompatibilities**

Not applicable

### **6.3 Shelf life**

2 years

### **6.4 Special precautions for storage**

KEEP OUT OF REACH OF CHILDREN

Keep the blister in the carton until required for use.

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Store at or below 25°C

### **6.5 Nature and contents of container**

Blister pack size: 24 lozenges

Lozenges are packed in blister made up of transparent clear 250 µm polyvinyl chloride PVC, coated with 40 g or 90 g polyvinylidene chloride pvdc; heat sealed to 20 µm aluminum foil.

The blister and tubes are packed in printed outer cardboard carton.

### **6.6 Special precautions for disposal**

Not applicable

## **7 HOLDER OF THE CERTIFICATE OF REGISTRATION**

Reckitt Benckiser Pharmaceuticals Pty Limited

8 Jet Park Road

Elandsfontein

1601

0860 11 11 00

## **8 REGISTRATION NUMBER**

45/16.4/0620

## **9 DATE OF FIRST AUTHORISATION/ RENEWAL OF THE AUTHORISATION**

06 March 2014

## **10 DATE OF REVISION OF THE TEXT**

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Date of Revision: 28 October 2025