

Registration number	45/16.4/0620
Product Proprietary name	Strepsils Warm Ginger
Dosage strength	Each lozenge contains: 2.4 Dichlorobenzyl alcohol 1,2 mg Amylmetacresol
Applicant	Reckitt Benckiser Pharmaceuticals (Pty) Ltd.
Date	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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System Organ Class	Frequency	Adverse Events
Immune System disorders	Less Frequent	Hypersensitivity ¹
Gastrointestinal Disorders	Not known	Glossodynia, oral discomfort

¹Hypersensitivity 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