PROFESSIONAL INFORMATION

Complementary Medicine
Discipline-Specific, Combination product

This unregistered medicine has not been evaluated by the SAHPRA for its quality, safety or intended use.

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

COLDEEZ® THROAT LOZENGES

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains**:**

Zinc gluconate providing Zinc (elemental)	27,88 mg 3,3 mg
Mentha x piperita L. *(*Peppermint) essential oil blend [Leaves, extract]	8,167 mg
Zingiber officinale (Ginger) [root, 4:1 extract providing 25 mg dried herb equivalent]	6,25 mg
Levomenthol crystals [purified extract of *Mentha arvensis* L. (Wild mint) oil]	5,25 mg

Contains sugar: Sucrose 1667,00 mg/lozenge
Glucose 1167,00 mg/lozenge

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A light-yellow circular lozenge with a characteristic honey lemon flavour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Soothing and cooling throat lozenge. Immune support.

4.2 Posology and method of administration

Posology

Adults and children 12 years and older: Dissolve one lozenge in the mouth every 2 to 3 hours. Do not exceed 6 lozenges in 24 hours.

Paediatric population

Use in children under the age of 12 years has not been established (See section 4.4)

Method of administration

For oral use.

4.3 Contraindications

- Hypersensitivity to the active ingredients or plants from the Lamiaceae or Zingiberaceae families, or to any of the excipients listed in section 6.1.
- Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency.
- Pregnancy
- Lactation
- Epilepsy
- Asthma
- Persistent or chronic cough
- Chronic lung conditions
- Concurrent use with other products containing menthol or eucalyptol or topical products containing camphor, menthol, eucalyptol and/or eucalyptus essential oil (See section 4.5).
- Use in children younger than 12 years of age. Safety has not been established.

4.4 Special warnings and precautions for use

COLDEEZ THROAT LOZENGES should be used with care in:

- Patients with an obstruction of the bile ducts, inflammation of the gallbladder or severe liver damage.
- Patients with gallstones or any other biliary disorder.
- Patients who already suffer from heartburn or hiatal hernia sometimes have an exacerbation of symptoms after taking peppermint oil, in which case treatment should be discontinued.
- Patients with inflamed and/or ulcerated conditions of the gastrointestinal tract.
- Patients with diabetes mellitus, as this product contains sugar. Each lozenge contains 1667 mg sucrose and 1167 mg glucose, which may affect the control of blood sugar.

If a hypersensitivity reaction occurs, use should be discontinued, and medical assistance should be sought immediately. This includes contact sensitivity on the mucosa (e.g. pain, swelling or blistering).

If symptoms persist or worsen, reoccur, or are accompanied by a fever, rash, or persistent headache, use should be discontinued, and a relevant health care provider should be consulted.

4.5 Interaction with other medicines and other forms of interaction

COLDEEZ THROAT LOZENGES should not be used with other products containing menthol or eucalyptol or topical products containing camphor, menthol, eucalyptol and/or eucalyptus essential oil. These products can have additive/synergistic effects, leading to increased potential for adverse reactions.

4.6 Fertility, pregnancy and lactation

Use in pregnancy and lactation is contraindicated (See section 4.3)

No fertility data available.

4.7 Effects on ability to drive and use machines

No studies have been performed on the effects on ability to drive and use machines.

4.8 Undesirable effects

a) Summary of the safety profile
Use should be discontinued if a hypersensitivity reaction occurs.

b) Tabulated summary of adverse reactions

Peppermint oil:

Classification	Frequency	Side effects
Immune system disorders	Unknown	Hypersensitivity reactions, which can include a sudden drop in blood pressure, difficulty breathing, bradycardia, muscle tremor, ataxia, nausea, dizziness and/or headache, contact sensitivity on the mucosa (e.g. pain, swelling or blistering), or erythematous skin rash.
Gastrointestinal disorders	Unknown	Heartburn, acid reflux, nausea, abdominal pain, diarrhoea, and dry mouth

Ginger:

Classification	Frequency	Side effects
Immune system disorders	Unknown	Hypersensitivity reactions
Gastrointestinal disorders	Unknown	Dyspepsia, nausea

Levomenthol:

Classification	Frequency	Side effects
Immune system disorders	Unknown	Hypersensitivity reactions
Gastrointestinal disorders	Unknown	Nausea, dyspepsia, diarrhoea,

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

4.9 Overdose
In overdose, side effects can be precipitated and/or increased by severity (see section 4.8).

Overdose may cause severe gastrointestinal symptoms, diarrhoea, rectal ulceration, epileptic convulsions, apnoea, nausea and disturbances in cardiac rhythms, ataxia and other CNS problems, probably due to the presence of menthol.

Treatment
Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties
Complementary Medicine.
D 33.7, Discipline Specific, Combination Product

5.2 Pharmacokinetic properties
The pharmacokinetic properties have not been established.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients
Honey flavouring
Lemon flavouring
Sucrose
Glucose
Citric acid monohydrate
Purified water
Sunset yellow colourant

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
2 years

6.4 Special precautions for storage
Store in a cool, dry place at or below 25 °C.
Protect from light and moisture.
Store in the original package.

6.5 Nature and contents of container
Carton containing two blisters, each with 12 light-yellow circular lozenges.

Pack size: 24 lozenges
Not all pack sizes may be marketed.

6.6 Special precautions for disposal
No special requirements.

7. PROSPECTIVE HOLDER OF CERTIFICATE OF REGISTRATION
Talo Consumer Solutions (Pty) Ltd.
30 Bell Crescent
Hennopspark Ext 7
Centurion
0172

8. REGISTRATION NUMBER
To be allocated.

9. DATE OF FIRST AUTHORISATION
To be allocated.

10. DATE OF REVISION OF TEXT
June 2026