

PROFESSIONAL INFORMATION

Complementary Medicine

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

S0

1. NAME OF THE MEDICINE

WOODS' PEPPERMINT LOZENGES (CHERRY)

Peppermint Essential Oil and Menthol lozenges.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each lozenge contains:

Peppermint Essential Oil 14,40 mg

Mentha x piperita L. (Peppermint Oil)

Mentha arvensis L. (Mint Oil)

Illicium verum Hook.f. (Star Anise)

Menthol (*Mentha arvensis*) 2,13 mg

[stem and leaf, steam distillation extraction]

Contains sugar:

Sucrose 1,67 g

Glucose Syrup 1,17 g

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Woods' Peppermint Lozenges are red, round and flat lozenges with cherry peppermint odour and taste.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Woods' Peppermint Lozenges give a soothing sensation in your throat and a fresh sensation on your breath.

4.2 Posology and method of administration

Slowly dissolve one (1) lozenge in the mouth as required.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

Patients with diabetes.

If you are pregnant or breastfeeding, do not use this product.

If you have epilepsy, asthma, persistent or chronic cough, or other chronic lung conditions, do not use this product.

4.4 Special warnings and precautions for use

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking **Woods' Peppermint Lozenges**.

Do not use with other products containing camphor, menthol, eucalyptol and/or eucalyptus essential oil.

If you experience pain, swelling or blistering, stop use and get medical help right away.

If symptoms persist or worsen, reoccur or are accompanied by a fever, rash or persistent headache, discontinue use and consult a relevant health care provider.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

The safety of **Woods' Peppermint Lozenges** in pregnancy and breastfeeding has not been established.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed. It is unlikely that treatment with **Woods' Peppermint Lozenges** will have any effect on the ability to drive and use machines.

4.8 Undesirable effects

Hypersensitivity to menthol and peppermint oil has been known to occur. The symptoms can include erythematous skin rash, burning discomfort, nausea, dizziness and/or headache, bradycardia, muscle tremor and ataxia. Discontinue use if any of these symptoms occur.

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. Healthcare providers are asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reactions Reporting Form" found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

4.9 Overdose

Ingestion of an overdose of menthol may cause severe abdominal pain, nausea, vomiting, vertigo, ataxia, drowsiness, and coma. Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

D 33.6 Western Herbal Complementary Medicine

The active ingredients in **Woods' Peppermint Lozenges** have a soothing and refreshing effect when the lozenge dissolve in the mouth.

5.2 Pharmacokinetic properties

Woods' Peppermint Lozenges have a local action. No absorption studies have been carried out.

5.3 Preclinical safety data

No additional preclinical information, relevant to the indication, is presented.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose,
Glucose Syrup,
Cherry Flavour,
Citric Acid,
Mint Flavour,
Orange Flavour,
Anise Oil,
Anethol,
Mango Flavour,
Ponceau 4R CI 16255,
Purified Water.

6.2 Incompatibilities

None known.

6.3 Shelf life

4 years.

6.4 Special precautions for storage

Store under normal storage conditions (15 °C – 30 °C), in a cool and dry place.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Aluminium foil sachets containing 6 individually wrapped lozenges.
15 or 3 sachets are packed in an outer carton box.

6.6 Special precautions for disposal

None.

7 HOLDER OF CERTIFICATE OF REGISTRATION

MDI HealthCare cc
374 Anderson Street
Menlo Park
Pretoria, 0081, South Africa
Tel: +27 12 460 1525

8 REGISTRATION NUMBER

To be allocated

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

To be allocated.

10 DATE OF REVISION OF THE TEXT

To be allocated.

Mozambique: General Sales; Reg. no.: xxx

Zambia: General Sales (GS); Reg. no.: xxx

Zimbabwe: General Sales (CMGS); Reg. no.: xxx