



# OPTIMED SOOTHERS COUGH LOZENGES

## D 33.6 Western Herbal Medicine. Complementary Medicine.

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

OPTIMED SOOTHERS COUGH LOZENGES (multiple substances, lozenges)

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

#### EACH LOZENGE CONTAINS:

<i>Glycyrrhiza glabra</i> L. (Licorice) [Root, as 60 mg of a 5:1 extract standardised to glycyrrhizic acid 2 %]	7 mg
<i>Mentha x piperita</i> L. (Peppermint) [Herb top flower & leaf, as 60 mg of a 5:1 extract standardised to menthol 2 %]	7 mg
<i>Terminalia bellirica</i> (Gaertn.) Roxb. (Baheda) [Fruit, as 80 mg of a 4:1 extract standardised to Tannin 2 %]	1,5 mg
<i>Zingiber officinale Roscoe</i> (Ginger) [Roots, as 60 mg of a 5:1 extract standardised to gingerols 2 %]	1 mg
<i>Curcuma longa</i> L. (Turmeric) [Rhizome, as 100 mg of a 5:1 extract standardised to curcuminoids 2 %]	1 mg

Contains sugar: 1,5 g sucrose and 1 g glucose.  
For a full list of excipients, see section 6.1.

### 3. PHARMACEUTICAL FORM

Lozenges. OPTIMED SOOTHERS COUGH LOZENGES are orange, round and flat lozenges with a sweet or strong licorice and peppermint taste.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

OPTIMED SOOTHERS COUGH LOZENGES is a complementary medicine that helps to soothe and relieve a sore throat and dry cough.

#### 4.2 Posology and method of administration

##### Posology

##### Adults and Children (4 years and older):

Take 1 to 2 lozenges, 3 to 4 times a day, as required. Slowly dissolve the lozenge in the mouth. Do not swallow whole or chew.

##### Paediatric population

Not suitable for use in children under the age of 4 years (see section 4.3. Contraindications).

##### Method of administration

Take orally.

#### 4.3 Contraindications

This product should not be used by patients who have an allergy or are hypersensitive to any of the ingredients. Not suitable for use in children under the age of 4 years.

#### 4.4 Special warnings and precautions for use

Do not exceed the stated recommended daily dose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking SOOTHER COUGH LOZENGES.

Consult your relevant health care provider prior to use:

- If you have a bleeding disorder, as concomitant use might increase the risk of bleeding.
- If you have diabetes, as it might also lower blood sugar levels.  
Your diabetic medications might need to be adjusted by your healthcare provider.

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

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

##### Interactions with Medicines

**Anticoagulant Medicines:** Concomitant use with anticoagulant and/or antiplatelet medicines may increase the risk of bleeding in some patients. Turmeric and ginger may have antiplatelet effects and may increase the risk of bleeding if used with anticoagulant or antiplatelet medicines.

**Antidiabetic Medicine:** Taking OPTIMED SOOTHERS COUGH LOZENGES with antidiabetic medicines might increase the risk of hypoglycaemia.

**Antihypertensive Medicine:** Theoretically, licorice might reduce the effects of antihypertensive medicines.

##### Interactions with Herbs and Supplements

**Anticoagulant Herbs and Supplements:** Concomitant use with anticoagulant and/or antiplatelet herbs and supplements may increase the risk of bleeding in some patients.

**Herbs and Supplements with Hypoglycemic Potential:** Theoretically, ginger and turmeric might have hypoglycemic effects.

##### Interactions with Foods

None known.

##### Interactions with Lab Tests

None known.

#### 4.6 Fertility, pregnancy and lactation

Not recommended for pregnant or lactating women. The use in pregnancy and lactation has not been established, therefore consult your doctor, pharmacist or other healthcare professional for advice (see section 4.4. Special warnings and precautions for use).

The effect on fertility is unknown.

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

There is no known effect on the ability to drive and use machines.

#### 4.8 Undesirable effects

Frequent side effects include abdominal pain, burping, dizziness, diarrhoea, dry mouth, heartburn and nausea. Allergic reactions including flushing, headache, and mouth sores may occur. Consuming large quantities continuously, can result in lower potassium levels, which can lead to abnormal heart rhythms, high blood pressure, swelling, lethargy, congestive heart failure.

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorization 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 "6.04 Adverse Drug Reactions Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>.

#### 4.9 Overdose

In overdose, side effects can be precipitated and/or be of increased severity (see section 4.8. Undesirable effects). Treatment is symptomatic and supportive.

### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1 Pharmacodynamic properties

##### D 33.6 Western Herbal Medicine

OPTIMED SOOTHERS COUGH LOZENGES is a complementary medicine containing licorice root, peppermint, baheda, ginger root and turmeric that helps to soothe and relieve a sore throat and dry cough.

*Licorice* has anti-inflammatory properties. The anti-inflammatory effects of licorice constituents are likely due to inhibition of pro-inflammatory cytokines and cellular degranulation, or oxidative or lytic activity.

In human research, a mixture of naturally-occurring plant oils, containing peppermint, exhibited marked anti-inflammatory activity in epithelial cells of the upper respiratory system.

*Ginger* is traditionally used in the treatment of upper respiratory tract infections, cough, respiratory distress, and bronchitis. Mechanisms of action are unclear. However, in laboratory research, ginger inhibits airway contraction and associated Ca<sup>2+</sup> signaling, possibly via blockade of plasma membrane Ca<sup>2+</sup> channels.

*Curcumin* appears to inhibit lung inflammation, airway hyperreactivity, and pulmonary emphysema. Potential mechanisms of action included the inhibition of inflammatory cytokines, reduced neutrophil levels, antioxidant effects, effects on NF- $\kappa$ B cell signaling, protection of the anti-inflammatory protein histone deacetylase-2, and decreased nitric oxide synthase activity.

#### 5.2 Pharmacokinetic properties

There is no clinical pharmacokinetic data available on OPTIMED SOOTHERS COUGH LOZENGES to clarify the pharmacokinetic properties.

### 6. PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

- Citric acid,
- Glucose,
- Menthol flavouring,
- Methyl Paraben,
- Mint flavour
- Orange flavouring,
- Propyl Paraben,
- Sucrose,
- Sunset Yellow colour (E110),
- Water.

#### 6.2 Incompatibilities

None known

#### 6.3 Shelf Life

The shelf life for OPTIMED SOOTHERS COUGH LOZENGES is 2 years.

#### 6.4 Special precautions for storage

Store at or below 30 °C in an airtight container, in a cool, dry place.

Protect from direct heat and sunlight.

KEEP OUT OF REACH OF CHILDREN.

#### 6.5 Nature and contents

OPTIMED SOOTHERS COUGH LOZENGES comes in:

8's: A carton box with one blister pack containing 8 lozenges.

80's: A green printed pouch containing 80 lozenges. Each lozenge is individually packed in printed, plastic sachets.

120's: A carton box with 20 blister packs containing 6 lozenges each.

#### 6.6 Special precautions for disposal

No special requirements.

### 7. HOLDER OF CERTIFICATE OF REGISTRATION

#### South Africa:

RP Pharma (Pty) Ltd  
6 Hennops Street  
Southdowns Estate  
Irene,  
0062.

#### Zambia:

Trade Kings Ltd.  
Plot No. 29381  
Nampundwe Road  
Light Industrial Area  
Lusaka, Zambia.

#### Manufactured by:

Trade Kings Ltd.  
Plot No. 29381  
Nampundwe Road  
Light Industrial Area  
Lusaka, Zambia.

### 8. REGISTRATION NUMBER

To be allocated.

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

Will be allocated by SAHPRA upon registration.


### 10. DATE OF REVISION OF THE TEXT

November 2023.

*Nerine du Plessis*

Responsible Pharmacist - RP Pharma (Pty) Ltd

15/02/2024

<b>JOB:</b> OPTIMED SOOTHERS COUGH LOZENGES PIL	<b>SIZE:</b> 210mm x 297mm
<b>STOCK:</b> Foil Substrate: <input type="checkbox"/> Clear Substrate: <input type="checkbox"/> White Substrate: <input type="checkbox"/> Paper: <input checked="" type="checkbox"/> Other: <input type="checkbox"/>	
<b>COLOURS:</b>  K	<b>FINISHING:</b> <input type="checkbox"/> Foil / Holographic Foil <input type="checkbox"/> Matte <input type="checkbox"/> Gloss <input type="checkbox"/> Spot UV <input type="checkbox"/> Daming <input type="checkbox"/> Embossing
<b>PLEASE CHECK CAREFULLY</b> Although we endeavour to proof accurately, we cannot accept responsibility for errors once proofs are signed and accepted by our clients.	

## OPTIMED SOOTHERS-HOESSUIGTABLETTE

**D 33.6 Westerse Kruiemedyne. Komplementêre medisyne.**

Hierdie ongeregisteerde medisyne is nie deur SAHPRA geëvalueer vir gehalte, veiligheid of bedoelde gebruik nie.

**SKEDULERINGSSTATUS:** S0

**1. NAAM VAN DIE MEDISYNE**

**OPTIMED SOOTHERS-HOESSUIGTABLETTE** (veelvuldige stowwe, suigtablette)

**2. KWALITATIEWE EN KWANTITATIEWE SAMESTELLING****ELKE SUIGTABLET BEVAT:**

<i>Glycyrrhiza glabra</i> L. (Soethout)	7 mg
[Wortel, as 60 mg van 'n 5:1-ekstrak gestandaardiseer na glisiriensuur 2 %]	
<i>Mentha x piperita</i> L. (Peperment)	7 mg
[Plant boonste blom en blaar, as 60 mg van 'n 5:1-ekstrak gestandaardiseer na mentol 2 %]	
<i>Terminalia bellirica</i> (Gaertn.) Roxb. (Baheda)	1,5 mg
[Vrug, as 80 mg van 'n 4:1-ekstrak gestandaardiseer na tannien 2 %]	
<i>Zingiber officinale Roscoe</i> (Gemmer)	1 mg
[Wortels, as 60 mg van 'n 5:1-ekstrak gestandaardiseer tot gingerol 2 %]	
<i>Curcuma longa</i> L. (Borrie)	1 mg
[Risoom, as 100 mg van 'n 5:1-ekstrak gestandaardiseer tot kurkuminoïede 2 %]	

Bevat suiker: 1,5 g sukrose en 1 g glukose.

Vir 'n volledige lys van onaktiewe bestanddele, sien afdeling 6.1.

**3. FARMASEUTIESE VORM**

Suigtablette. OPTIMED SOOTHERS-HOESSUIGTABLETTE is oranje, ronde en plat suigtablette met 'n soet of sterk drop- en pepermentsmaak.

**4. KLINIESE GEGEWENS****4.1 Terapeutiese aanduidings**

OPTIMED SOOTHERS-HOESSUIGTABLETTE is 'n komplementêre medisyne wat help om 'n seer keel en droë hoës te streef en te verlig.

**4.2 Dosering en toedieningsmetode****Dosering****Volwassenes en kinders (4 jaar en ouer):**

Neem 1 tot 2 suigtablette, 3 tot 4 keer per dag, soos nodig. Los die suigtablette stadig in die mond op. Moenie heel insluk of kou nie.

**Pediatriese bevolking**

Nie geskik vir gebruik by kinders jonger as 4 jaar nie (sien afdeling 4.3. Kontra-indikasies).

**Metode van toediening**

Neem mondeliks in.

**4.3 Kontra-indikasies**

Hierdie produk moenie gebruik word deur pasiënte wat allergies of hipersensitief is vir enige van die bestanddele nie. Nie geskik vir kinders jonger as 4 jaar nie.

**4.4 Spesiale waarskuwings en voorsorgmaatreëls vir gebruik**

Moenie die genoemde aanbevole daaglikse dosis oorskry nie. As u dokter vir u gesê het dat u onverdraagsaamheid teenoor sommige suikers het, kontak u dokter voordat u OPTIMED SOOTHERS-HOESSUIGTABLETTE neem.

Raadpleeg u relevante gesondheidsorgverskaffer voor gebruik:

- As u 'n bloedingsteuring het, aangesien meegaande gebruik die risiko van bloeding kan verhoog.
- As u diabetes het, want dit kan ook bloedsuikervlakke verlaag. U diabetiese medikasie moet dalk deur u gesondheidsorgverskaffer aangepas word.

Moenie saam met ander produkte gebruik wat kamfer, mentol, eukaliptool en/of bloekom- essensiële olie bevat nie. As u pyn, swelling of blaasvorming ervaar, hou op om te gebruik en kry dadelik mediese hulp. As simptome voortduur of vererger, herhaal of gepaard gaan met koors, uitslag of aanhoudende hoofpyn, staak die gebruik en raadpleeg 'n relevante gesondheidsorgverskaffer. As u epilepsie, asma, aanhoudende of chroniese hoës, of ander chroniese langtoestande het, moenie hierdie produk gebruik nie.

**4.5 Interaksie met ander medisyne en ander vorme van interaksie****Interaksies met medisyne**

**Antistollingsmiddels:** Meegaande gebruik met antistollingsmiddels en/of antiplaatjemedisyne kan die risiko van bloeding by sommige pasiënte verhoog. Borrie en gemmer kan antiplaatjie-effekte hê en kan die risiko van bloeding verhoog as dit saam met antistollingsmiddels of antiplaatjemedisyne gebruik word.

**Antidiabetiese medisyne:** As OPTIMED SOOTHERS-HOESSUIGTABLETTE saam met antidiabetiese medisyne geneem word, kan dit die risiko van hipoglisemie verhoog.

**Antihypertensiewe medisyne:** Teoreties kan drop die effekte van antihypertensiewe medisyne verminder.

**Interaksies met kruie en aanvullings**

**Antistollingskruie en -aanvullings:** Meegaande gebruik met antistollings- en/of antiplaatjekruie en -aanvullings kan die risiko van bloeding by sommige pasiënte verhoog.

**Kruie en aanvullings met hipoglisemiese potensiaal:** Teoreties kan gemmer en borrie hipoglisemiese effekte hê.

**Interaksies met voedsel**

Geen bekend nie.

**Interaksies met laboratoriumtoets**

Geen bekend nie.

**4.6 Vrugbaarheid, swangerskap en laktasie**

Nie aanbeveel vir swanger of borsvoedende vroue nie. Die gebruik gedurende swangerskap en borsvoeding is nie vasgestel nie, raadpleeg dus u dokter, apteker of ander gesondheidsorgdeskundige vir advies (sien afdeling 4.4. Spesiale waarskuwings en voorsorgmaatreëls vir gebruik). Die uitwerking op vrugbaarheid is onbekend.

**4.7 Uitwerking op die vermoë om te bestuur of masjinerie te gebruik**

Daar is geen bekende uitwerking op die vermoë om te bestuur en masjinerie te gebruik nie.

**4.8 Ongewenste effekte**

Neuwe-effekte wat dikwels voorkom, sluit in buikpyn, winde opbreek, duiseligheid, diarree, droë mond, soorbrand en naarheid. Allergiese reaksies insluitende gloede, hoofpyn en mondseer kan voorkom. Voortdurende inname van groot hoeveelhede kan laer kaliumvlakke tot gevolg hê, wat kan lei tot abnormale hartritmie, hoë bloeddruk, swelling, lusteloosheid, kongestiewe hartversaking.

**Rapportering van vermoedelike ongewenste reaksies**

Dit is belangrik om vermoedelike ongewenste reaksies ná magtiging van die medisyne te rapporteer. Dit laat voortgesette monitering van die voordeel/risiko-balans van die medisyne toe. Gesondheidsorgverskaffers word gevra om enige vermoedelike ongewenste reaksies by SAHPRA te rapporteer via die rapporteringsvorm vir ongewenste reaksies op middels ("6.04 Adverse Drug Reaction Reporting Form"), aanlyn gevind onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>.

**4.9 Oordosering**

Met oordosering kan neuwe-effekte verhaas word en/of van verhoogde erns wees (sien Afdeling 4.8). Ongewenste effekte). Behandeling is simptomaties en ondersteunend.

**5. FARMAKOLOGIESE EIENSKAPPE****5.1 Farmakodinamiese eienskappe**

D 33.6 Westerse Kruiemedyne

OPTIMED SOOTHERS-HOESSUIGTABLETTE is 'n komplementêre medisyne wat soethout, peperment, baheda, gemmerwortel en borrie bevat en help om 'n seer keel en droë hoës te streef en te verlig.

Drop het anti-inflammatoriese eienskappe. Die anti-inflammatoriese effekte van die bestanddele van drop is waarskynlik te wyte aan inhibisie van pro-inflammatoriese sitokiene en sellulêre degranulering, of oksidatiewe of litiese aktiviteit.

In navorsing op mense het 'n mengsel van natuurlik voorkomende plantolies, wat peperment bevat, merkbare anti-inflammatoriese aktiviteit in epiteelselle van die bolugwegstelsel getoon.

Gemmer word tradisioneel gebruik in die behandeling van bolugweginfeksies, hoës, respiratoriese nood en brongitis. Werkingsmeganismes is onduidelik. In laboratoriumnavorsing inhibeer gemmer egter lugwegkontraksie en gepaardgaande Ca(2+)-seine, moontlik via blokkering van plasmamembraan-Ca(2+)-kanale.

Kurkumien inhibeer skynbaar longontsteking, lugweghiperaktiwiteit en pulmonêre emfiseem. Potensiële werkingsmeganismes sluit in die inhibisie van inflammatoriese sitokiene, verlaagde neutrofielvlakke, antioksidanteffekte, effekte op NF-kappa-B sel-seine, beskerming van die anti-inflammatoriese proteïen histoondeasetilase-2, en verminderde stikstofoksiedsintaseaktiwiteit.

**5.2 Farmakokinetiese eienskappe**

Daar is geen kliniese farmakokinetiese data beskikbaar oor OPTIMED SOOTHERS-HOESSUIGTABLETTE om die farmakokinetiese eienskappe te verduidelik nie.

**6. FARMASEUTIESE GEGEWENS****6.1 Lys van onaktiewe bestanddele**

- Citroensuur,
- Glukose,
- Mentolgeursel,
- Metielparabeen,
- Kruisementgeur
- Lemoengeursel,
- Propielparabeen,
- Sukrose,
- Sunset Yellow-kleur (E110),
- Water

**6.2 Onversoenbaarheid**

Geen bekend nie

**6.3 Raklewe**

Die raklewe vir OPTIMED SOOTHERS-HOESSUIGTABLETTE is 2 jaar.

**6.4 Spesiale voorsorgmaatreëls vir bewaring**

Bewaar by of onder 30 °C in 'n lugdigte houër, in 'n koel, droë plek.

Beskerm teen direkte hitte en sonlig.

HOU BIJTE BEREIK VAN KINDERS.

**6.5 Aard en inhoud**

OPTIMED SOOTHERS-HOESSUIGTABLETTE kom in:

8's: 'n Kartondoos met een stolppakkie wat 8 suigtablette bevat.

80's: 'n Groen gedrukte sakkie wat 80 suigtablette bevat. Elke suigtablette word individueel in 'n gedrukte plastieksakkie verpak.

120's: 'n Kartondoos met 20 stolppakkies wat 6 suigtablette bevat.

**6.6 Spesiale voorsorgmaatreëls vir wegdoening**

Geen spesiale vereistes nie.

**7. HOUER VAN REGISTRASIESERTIFIKAAT**

**Suid-Afrika:**  
RP Pharma (Edms.) Bpk.  
Hennopsstraat 6  
Southdowns Estate  
Irene,  
0062.

**Zambië:**  
Trade Kings Bpk.  
Plot No. 29381  
Nampundwe Road  
Light Industrial Area  
Lusaka, Zambia.

**Manufactured by:**  
Trade Kings Bpk.  
Plot No. 29381  
Nampundwe Road  
Light Industrial Area  
Lusaka, Zambia.

**8. REGISTRASIE-NOMMER**

Moet toegeken word.

**9. DATUM VAN EERSTE MAGTIGING/HERNUWING VAN DIE MAGTIGING**

Sal by registrasie deur SAHPRA toegeken word.


**10. DATUM VAN HERSIENING VAN DIE TEKS**

November 2023.

*Nerine du Plessis*

Responsible Pharmacist - RP Pharma (Pty) Ltd

15/02/2024

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