

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S0**

PROPRIETARY NAME, STRENGTH AND DOSAGE FORM:

STREPSILS ORIGINAL LOZENGE

STREPSILS SOOTHING HONEY AND LEMON LOZENGE

2,4-dichlorobenzyl alcohol 1,2 mg and amylmetacresol 0,6 mg.

Read all of this leaflet carefully because it contains important information for you
STREPSILS ORIGINAL or **STREPSILS SOOTHING HONEY AND LEMON** is available without a doctor's prescription, for you to treat a mild illness. Nevertheless, you still need to take **STREPSILS ORIGINAL** or **STREPSILS SOOTHING HONEY AND LEMON** carefully to get the best results from it.

Keep this leaflet. You may need to read it again.

Do not share this medicine with any other person.

Ask your pharmacist if you need more information or advise.

You must see a doctor if your symptoms worsen or do not improve after 2 days.

1. WHAT STREPSILS ORIGINAL OR STREPSILS SOOTHING HONEY AND LEMON CONTAINS:

- The active substances are Amylmetacresol 0,6 mg, 2,4 Dichlorobenzyl Alcohol 1,2 mg,
- Other ingredients are
 - Strepsils original:
Carmosine edicol (E 122), liquid sucrose, liquid glucose, levomenthol, Ponceau 4R (E124), peppermint oil, star anise oil, tartaric acid.
 - Strepsils Soothing Honey & Lemon
Honey, liquid sucrose, liquid glucose, peppermint oil, Quinolene yellow (E104) terpeneless lemon oil, tartaric acid.
 - Contains sugar 2,5 g

2. WHAT STREPSILS ORIGINAL OR STREPSILS SOOTHING HONEY AND LEMON IS USED FOR:

STREPSILS ORIGINAL: is used for the relief of minor mouth and throat infections.

It is also used for the relief of coughs due to colds and allergies.

STREPSILS SOOTHING HONEY AND LEMON is used for relief of minor mouth and throat infections.

3. BEFORE YOU TAKE STREPSILS ORIGINAL OR STREPSILS SOOTHING HONEY AND LEMON:

Do not take STREPSILS ORIGINAL OR STREPSILS SOOTHING HONEY AND LEMON:

- If you are hypersensitive (allergic) to (active substance) or any of the other ingredients of **STREPSILS ORIGINAL OR STREPSILS SOOTHING HONEY AND LEMON**
- Children under 6 years of age.

Taking other medicine with STREPSILS ORIGINAL OR STREPSILS SOOTHING HONEY AND LEMON:

What should you avoid when you are taking STREPSILS ORIGINAL OR STREPSILS SOOTHING HONEY AND LEMON:

No known interactions.

Pregnancy and breast-feeding

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking this medicine.

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

It is unknown whether 2, 4-dichlorobenzyl alcohol, Amylmetacresol or metabolites are excreted in human milk.

Risk to the newborns / infants cannot be excluded.

Driving and using machinery:

- Negligible influence

Taking other medicine with STREPSILS ORIGINAL OR STREPSILS SOOTHING HONEY AND LEMON:

Always tell your healthcare professional if you are taking any other medicine.

4. HOW TO TAKE STREPSILS ORIGINAL OR STREPSILS SOOTHING HONEY AND LEMON:

This medicine should not be taken by children below 6 years of age

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you. Check with your doctor or pharmacist or nurse if you are not sure.

Do not share medicines prescribed for you with any other person.

Unless otherwise prescribed by your doctor, the standard dose is:

Adults and children over 6 years

- The lowest effective dose should be used for the shortest duration necessary to relieve Symptoms.
- Dissolve one lozenge slowly in the mouth every 2 to 3 hours.
- Do not exceed 12 lozenges in any 24-hour period.

If you take more STREPSILS ORIGINAL OR STREPSILS SOOTHING HONEY AND LEMON than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

In the unlikely event of an overdose, serious side effects are not expected.

Some gastrointestinal discomfort may be experienced.

5. POSSIBLE SIDE EFFECTS:

STREPSILS ORIGINAL OR STREPSILS SOOTHING HONEY AND LEMON can have side effects

System Organ Class	Frequency	Adverse Events
Immune System Disorders	Not known	Hypersensitivity ^{ab}
Gastrointestinal Disorders	Not known	Abdominal pain ^{ab} , nausea ^{ab} , oral discomfort ^{ab}
Skin and Subcutaneous Tissue Disorders	Not known	Rash ^{ab}

^a2, 4-dichlorobenzyl alcohol ^bamylmetacresol

Not all side effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice. If you notice any side effects not mentioned in this leaflet, please inform your doctor or Pharmacist.

6. STORING AND DISPOSING OF STREPSILS ORIGINAL OR STREPSILS SOOTHING HONEY AND LEMON:

Store all medicines out of reach of children.

Store at or below 25°C

Do not use after the expiry date stated on the carton.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets)

7. PRESENTATION

Strepsils Original: Cartons containing 24 blister packed lozenges

Strepsils Soothing Honey and Lemon: Cartons containing 8, 10 or 24 blister packed lozenges

8. IDENTIFICATION:

Strepsils Original: A red circular lozenge with an odour predominantly of aniseed with a characteristic acid taste and the Strepsils brand icon intagliated on both sides

Strepsils Soothing Honey and Lemon:

A yellow, circular lozenge with a taste predominantly of honey and lemon and the Strepsils brand icon intagliated on both sides

9. REGISTRATION/REFERENCE NUMBER:

STREPSILS ORIGINAL: H1468 (ACT 101/1965)

STREPSILS SOOTHING HONEY AND LEMON: E/16.4/46

10. NAME, BUSINESS ADDRESS AND TELEPHONE NUMBER OF THE OF CERTIFICATE OF REGISTRATION:

Reckitt Benckiser Pharmaceuticals (Pty) Ltd
8 Jet Park Road
Elandsfontein

1601
+2711 871 1611

11. DATE OF PUBLICATION OF THIS PATIENT INFORMATION LEAFLET:

Date on the registration certificate:

Strepsils Soothing Honey and Lemon: 09 March 1972

Strepsils Original: Old Medicine

Date of the most recently revised patient information leaflet: 20 December 2019

Please go to the link for access to the corresponding PI: <https://cpdcentre.co.za/product-inserts/Strepsils-Original-Soothing-Honey-Lemon.pdf>

<i>Strepsils Soothing Honey and Lemon</i>	
Namibia	90/16.4/00470 (NS0)
Botswana	B9301950 (S4)
Zambia	133/019 (GS)
Zimbabwe	74/20.3.5/0274 (HR)

<i>Strepsils Original</i>	
Botswana	B9301940 (S4)
Namibia	02 1000306 (NS0)
Zimbabwe	77/20.3.5/842 (HR)

SKEDULERINGSSTATUS: **S0**

EIENDOMSNAAM, STERKTE EN DOSEERVORM:

STREPSILS ORIGINAL SUIGTABLET

STREPSILS SOOTHING HONEY AND LEMON SUIGTABLET

2,4-dichloorbenzylalkohol 1,2 mg en amymetrakresol 0,6 mg.

Lees hierdie hele pamflet noukeurig deur want dit bevat belangrike inligting vir u

STREPSILS ORIGINAL OR STREPSILS SOOTHING HONEY AND LEMON is beskikbaar sonder 'n voorskrif van 'n dokter, vir jou om matige siektes te behandel.

Ongeag moet u steeds STREPSILS ORIGINAL of STREPSILS SOOTHING HONEY AND LEMON versigtig gebruik om die beste resultate daaruit te kry.

- Bewaar hierdie pamflet. Dit mag nodig wees om dit weer te lees.
- Moet nie hierdie medisyne met enige ander persoon deel nie.
- Vra u apteker indien u meer inligting of advies benodig.
- Sien u dokter indien u simptome vererger of na 2 dae nie verbeter nie.

1. WAT HIERDIE STREPSILS ORIGINAL OF STREPSILS HONEY AND LEMON BEVAT:

* Die aktiewe bestanddeel is Amielmetakresol 0,6 mg, 2,4 dichloorbensielalkohol 1,2 mg,

* Die ander bestanddele is

Strepsils original

Carmiosine edicol (E122), vloeibare sukrose, vloeibare glukose, levomenthol, Ponceau 4R (E124), pepermentolie, steranysolie, wynsteensuur.

Strepsils Soothing Honey and Lemon

Heuning, vloeibare sukrose, vloeibare glukose, pepermentolie, kinoliengeel (E104) terpenlose suurlimoenolie, wynsteensuur.

Bevat suiker 2,5 g

2. WAT STREPSILS ORIGINAL OF STREPSILS SOOTHING HONEY AND LEMON VOOR GEBRUIK WORD:

STREPSILS ORIGINAL word gebruik vir die verligting van geringe mond en keel infeksies.

Dit word ook gebruik vir die verligting van verkoue en allergieë.

STREPSILS SOOTHING HONEY AND LEMON word gebruik vir die verligting van geringe mond- en keelinfeksies.

3. VOOR JY STREPSILS ORIGINAL OF STREPSILS SOOTHING HONEY AND LEMON NEEM: Moet nie STREPSILS ORIGINAL OR STREPSILS SOOTHING HONEY AND LEMON neem:

- Indien u hipersensitief (allergies) is vir (aktiewe bestanddele) of enige van die ander bestanddele van **STREPSILS ORIGINAL OF STREPSILS SOOTHING HONEY AND LEMON** nie
- Kinders jonger as 6 jaar

Die neem van ander medisyne met **STREPSILS ORIGINAL OF STREPSILS SOOTHING HONEY AND LEMON:**

Vermy die volgende as u STREPSILS ORIGINAL OR STREPSILS SOOTHING HONEY AND LEMON neem

Geen bekende interaksies

Swangerskap en borsvoeding

Indien u swanger is of u baba borsvoed, raadpleeg u dokter, apteker of ander professionele gesondheidswerker vir advies voor die neem van hierdie medisyne.

Daar is geen of beperkte aantal data van die gebruik van Amielmetakresol & 2,4 dichloorbensielalkohol.

Dit is onbekend of 2,4 dichloorbensielalkohol, Amielmetakresol of

Metaboliete word uitgeskei in borsmelk.

Gevaar tot pasgebore babas / babas kan nie uitgesluit word nie.

Bestuur en gebruik van masjinerie:

Nalatige invloed

Die neem van ander medisyne met STREPSILS ORIGINAL OF STREPSILS SOOTHING HONEY AND LEMON:

Lig altyd u professionele gesondheidswerker in as u enige ander medikasie neem.

4. HOE OM STREPSILS ORIGINAL OF STREPSILS SOOTHING HONEY AND LEMON TE NEEM:

Die medisyne moet nie geneem word deur kinder jonger as 6 jaar nie.

Neem altyd **STREPSILS ORIGINAL OF STREPSILS SOOTHING HONEY AND LEMON** presies soos in die pamflet beskryf word, of soos deur u dokter, apteker of verpleegkundige aanbeveel is. Raadpleeg u dokter, apteker of verpleegster as u nie seker is nie.

Moet nie medisyne wat aan u voorgeskryf is, deel met enige ander persoon nie.

Tensy u dokter anders voorskryf, is die standaard dosis:

Volwasse en kinders oor 6 jaar

- Die laagste effektiewe dosis behoort gebruik te word vir die korste moontlike tyd om simptome te verlig.
- Los een suigtablet op in die mond elke 2 tot 3 ure.
- Moet nie meer as 12 suigtablette neem in enige 24 uur periode nie.

Indien u meer STREPSILS ORIGINAL OF STREPSILS SOOTHING HONEY AND LEMON neem as wat u behoort:

In die geval van 'n oordosis, raadpleeg u dokter of apteker. Indien daar nie een beskikbaar is nie, kontak die naaste hospitaal of gifbeheersentrum.

In die onwaarskynlike geval van 'n oordosis, word ernstige newe-effekte nie verwag nie.

Daar mag spysverteringskanaal ongemak ervaar word.

5. MOONTIKE NEWE-EFFEKTE

STREPSILS ORIGINAL OF STREPSILS SOOTHING HONEY AND LEMON mag newe-effekte hê

Liggaamstelsel	Frekwensie	Nadelige Gevolge
Immunitietstelsel Versteuring	Onbekend	Hipersensitiwiteit ^{ab}
Spysverteringskanaal Versteuring	Onbekend	Maagpyn ^{ab} naarheid ^{ab} , orale ongemak ^{ab}
Vel- en onderhuidse weefselafwykings	Onbekend	Veluitslag ^{ab}

^a2, 4-dichloorbenzylalkohol ^bamielmetakresol

Nie alle newe-effekte wat vir hierdie medisyne aangemeld word, is in hierdie pamflet ingesluit nie.

Indien u algemene gesondheid vererger tydens die gebruik van hierdie medisyne, raadpleeg u dokter, apteker.

Indien u let op enige newe-effekte wat nie in hierdie blaaie genoem word nie, raadpleeg u dokter of apteker.

6. BERGINGSAAWYSINGS EN VERWYDERING VAN STREPSILS ORIGINAL OF STREPSILS SOOTHING HONEY AND LEMON

Hou alle medisyne buite die bereik van kinders.

Bewaar teen of benede 25 ° C.

Moet nie die produk gebruik na verloop van die vervaldatum wat op die karton aangedui word nie.

Besorg alle ongebruikte medisyne terug aan u apteker.

Moet nie wegdoen met ongebruikte medisyne in dreine en rioolstelsels (bv. Toilette) nie.

7. AANBIEDING:

Strepsils Original: Kartonne bevat 24 stulpstrook verpakte suigtablette

Strepsils Soothing Honey and Lemon: Kartonne bevat 8, 10 of 24 stulpstrook verpakte suigtablette

8. IDENTIFIKASIE

Strepsils Original:

'n rooi sirkelvormige suigtablet met 'n hoofsaaklik anysagtige reuk en 'n kenmerkende suuragtige smaak en die Strepsils handelsmerk beide kante ingekerf

Strepsils Soothing Honey and Lemon:

'n geel, sirlvormige suigtablet met 'n smaak hoofsaaklik van heuning en suurlemoen en die Strepsils handelsmerk beide kante ingekerf

9. REGISTRASIENOMMER/VERWYSINGSNOMMER:

STREPSILS ORIGINAL: H1468 (ACT 101/1965)

STREPSILS SOOTHING HONEY AND LEMON: E/16.4/46

10. NAAM, BESIGHEIDSADRES EN TELEFOONNOMMER VAN DIE HOUER VAN DIE SERTIFIKAAT VAN REGISTRASIE:

Reckitt Benckiser Pharmaceuticals (Edms) Bpk

8 Jet Park Road

Elandsfontein

1601

+2711 871 1611

11. DATUM VAN PUBLIKASIE VAN DIE PASIËNT-INLIGTINGSVOUBILJET:

Datum op die registrasiesertifikaat:

Strepsils Soothing Honey and Lemon: 09 Maart 1972

Strepsils Original: Ou medisyne

Datum op die mees onlangste pasiënt-inligtingsvoubiljet: 20 Desember 2019

Gaan asseblief na die web adres vir die ooreenstemmende professionele informasie:

<https://cpdcentre.co.za/product-inserts/Strepsils-Original-Soothing-Honey-Lemon.pdf>