

LOZEZIL®

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS:

S0

LOZEZIL® Blackcurrant
LOZEZIL® Honey Lemon
LOZEZIL® Lemon
LOZEZIL® Orange

2, 4 Dichlorobenzyl Alcohol 1,2 mg; Amylmetacresol 0,6 mg
Contains sugar:
Each lozenge contains 1618,0 mg sucrose and 1038,0 mg liquid glucose.

Read all of this leaflet carefully because it contains important information for you.

LOZEZIL® is available without a doctor's prescription for you to treat a mild illness. Nevertheless, you still need to take LOZEZIL® carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share LOZEZIL® with any other person.
- Ask your pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve after 2 days.

What is in this leaflet

1. What LOZEZIL® is and what it is used for
2. What you need to know before you take LOZEZIL®
3. How to take LOZEZIL®
4. Possible side effects
5. How to store LOZEZIL®
6. Contents of the pack and other information

1. What LOZEZIL® is and what it is used for

LOZEZIL® contains two antiseptic medicines Amylmetacresol and 2,4-Dichlorobenzyl Alcohol. These are used for the symptomatic relief of minor mouth and throat infections.

These ingredients are both mild antiseptics which kill the bacteria associated with mouth and throat infections.

2. What you need to know before you take LOZEZIL®

Do not take LOZEZIL® if:

- you are hypersensitive (allergic) to 2,4-dichlorobenzyl alcohol, amylmetacresol, or any of the ingredients (listed in section 6).
- the patient is a child under 6 years old.
- you have an intolerance to certain sugars such as fructose, glucose-galactose and sucrose-isomaltose.

Warnings and Precautions

If symptoms persist, have not improved, or have worsened after 2 days, consult a doctor or healthcare professional.

This product contains sucrose and glucose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this product.

Children

Children under 6 years old should not use LOZEZIL®.

Other medicines and LOZEZIL®

Always tell your healthcare provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)
No clinically significant interactions are known.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines

It is not always possible to predict to what extent LOZEZIL® may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which LOZEZIL® affects them.

LOZEZIL® contains glucose and sucrose

If you have a rare hereditary problem of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltose insufficiency, you should not take LOZEZIL®.

3. How to take LOZEZIL®

Do not share medicines prescribed for you with any other person
Always use LOZEZIL® exactly as described in this leaflet or as your doctor, pharmacist or nurse have told you. Check with your doctor, pharmacist or nurse if you are not sure.

How LOZEZIL® is given

Lozenge are to be dissolved in mouth, slowly.

How much LOZEZIL® is given

Remove one lozenge from the foil blister packaging.
Place lozenge into the mouth allowing it to dissolve slowly.
Dissolve one lozenge slowly in the mouth every 2 – 3 hours.
Do not exceed 12 lozenges in any 24-hour period

If you take more LOZEZIL® than you should:

You may experience stomach discomfort. Do not take any more of this product. In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take LOZEZIL®

Do not take a double dose to make up for forgotten individual doses.

4. Possible side effects

LOZEZIL® can have side effects.

Not all side effects reported for LOZEZIL® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while receiving this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking LOZEZIL® and tell your doctor immediately or go to the casualty department at your nearest hospital:

- If you experience any hypersensitivity to this product i.e. difficulty in breathing, swelling of the face, neck, tongue or throat and rash (severe allergic reactions).

If any of these side effects gets serious please tell your doctor or pharmacist.

Tell your doctor if you notice any of the following:

Side-effects – frequency not known

- Itching, burning sensation or pain in the tongue
- Sore or uncomfortable feeling in the mouth area

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”; found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of LOZEZIL®.

5. How to store LOZEZIL®

Store all medicines out of reach of children.

Store at or below 25 °C.

Store in the original package.

6. Contents of the pack and other information

What LOZEZIL® contains

The active ingredients are: 1,2 mg 2,4-dichlorobenzyl alcohol and 0,6 mg amylmetacresol

The other ingredients are:

For Blackcurrant Lozenges:

Sucrose, Liquid glucose, Citric acid monohydrate, Mentha oil, Black currant flavour, Colour Ponceau 4R, Colour Black PN.

For Honey Lemon Lozenges:

Sucrose, Liquid glucose, Mentha oil, Honey flavour, Essence lemon oil, Caramel, Colour Ponceau 4R, Riboflavin phosphate sodium.

For Lemon Lozenges:

Sucrose, Liquid glucose, Citric acid monohydrate, Mentha oil, Lemon oil concentrate, Anise oil, Riboflavin phosphate sodium.

For Orange Lozenges:

Sucrose, Liquid glucose, Citric acid monohydrate, Mentha oil, Orange oil sweet excellent, Anise oil, Riboflavin phosphate sodium, Colour Ponceau 4R.

What LOZEZIL® looks like and contents of the pack

Silver opaque aluminium and clear transparent PVC/PE/PVDC foil blisters, with 12 lozenges per blister and 24 lozenges packed in an outer carton along with leaflet.

Holder of Certificate of Registration

Biotech Laboratories (Pty) Ltd
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400 16th Road, Randjespark
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Tel. no: 011 848 3050

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30 August 2022

Registration number

LOZEZIL® BLACKCURRANT: 50/16.4/2301
LOZEZIL® HONEY LEMON: 50/16.4/2311
LOZEZIL® LEMON: 50/16.4/2316
LOZEZIL® ORANGE: 50/16.4/2311

LOZEZIL®

PASIËNTINLIGTINGSBLAD

SKEDULERINGSSTATUS:

S0

LOZEZIL® Blackcurrant
LOZEZIL® Honey Lemon
LOZEZIL® Lemon
LOZEZIL® Orange

2, 4 Dichloorbensiel Alkohol 1,2 mg; Amielmetakresol 0,6 mg
Bevat suiker:
Elke suigtablet bevat 1618,0 mg sukrose en 1038,0 mg vloeibare glukose.

Lees die hele pamflet noukeurig deur, want dit bevat belangrike inligting vir jou.

LOZEZIL® is beskikbaar sonder 'n dokter se voorskrif vir jou om 'n ligte siekte te behandel. Nietemin moet jy nog steeds LOZEZIL® versigtig gebruik om die beste resultate daaruit te kry.

- Bewaar hierdie pamflet. Jy sal dit dalk weer moet lees.
- Moenie LOZEZIL® met enige ander persoon deel nie.
- Vra jou apteker as jy meer inligting of advies benodig.
- Jy moet 'n dokter sien as jou simptome vererger of nie na 2 dae verbeter nie.

Wat is in hierdie pamflet

1. Wat is LOZEZIL® en waarvoor dit gebruik word
2. Wat jy moet weet voordat jy LOZEZIL® neem
3. Hoe om LOZEZIL® te neem
4. Moontlike newe-effekte
5. Hoe om LOZEZIL® te bewaar
6. Inhoud van die pakkie en ander inligting

1. Wat is LOZEZIL® en waarvoor dit gebruik word

LOZEZIL® bevat twee antiseptiese medisyne Amielmetalresol en 2,4-Dichloorbensiel Alkohol. Dit word gebruik vir die simptomatiesie verligting van geringe mond- en keelinfeksies. Hierdie bestanddele is albei ligte antiseptika wat die bakterieë wat verband hou met mond- en keelinfeksies doodmaak.

2. Wat jy moet weet voordat jy LOZEZIL® neem

Moenie LOZEZIL® neem as:

- jy is hipersensitief (allergies) vir 2,4-dichloorbensielalkohol, amielmetakresol, of enige van die bestanddele (gelys in afdeling 6).
- die pasiënt 'n kind jonger as 6 jaar oud is.
- jy het 'n onverdraagsaamheid teenoor sekere suikers soos fruktose, glukose-galaktose en sukrose-isomaltose.

Waarskuwings en voorsorgmaatreëls

As simptome voortduur, nie verbeter het nie, of na 2 dae vererger het, raadpleeg 'n dokter of gesondheidsorgverskaffer. Hierdie produk bevat sukrose en glukose. As jy deur jou dokter gesê is dat jy 'n onverdraagsaamheid teenoor sommige suikers het, kontak jou dokter voordat jy hierdie produk neem.

Kinders

Kinders jonger as 6 jaar oud moet nie LOZEZIL® gebruik nie.

Ander medisyne en LOZEZIL®

Vertel altyd jou gesondheidsorgverskaffer as jy enige ander medisyne neem. (Dit sluit alle komplementêre of tradisionele medisyne in.) Geen klinies betekenisvolle interaksies is bekend nie.

Swangerskap en borsvoeding

As jy swanger is of borsvoed, dink jy is dalk swanger of beplan om 'n baba te hê, raadpleeg asseblief jou dokter, apteker of ander gesondheidsorgverskaffer vir advies voordat jy hierdie medisyne neem.

Bestuur en gebruik van masjينة

Die is nie altyd moontlik om te voorspel tot watter mate LOZEZIL® met die daaglikse aktiwiteite van 'n pasiënt kan inmeng nie. Pasiënte moet verseker dat hulle nie aan bogenoemde aktiwiteite deelneem totdat hulle bewus is van die mate waarin LOZEZIL® hulle affekteer nie.

LOZEZIL® bevat glukose en sukrose

As jy 'n seldsame oorerflike probleem van fruktose-onverdraagsaamheid, glukose-galaktose-wanabsorpsie of sukrose-isomaltose-tekort het, moet jy nie LOZEZIL® neem nie.

3. Hoe om LOZEZIL® te neem

Moenie medisyne wat vir jou voorgeskryf is met enige ander persoon deel nie. Gebruik LOZEZIL® altyd presies soos beskryf in hierdie pamflet of soos jou dokter, apteker of verpleegster jou vertel het. Gaan na jou dokter, apteker of verpleegster as jy nie seker is nie.

Hoe LOZEZIL® gegee word

Die suigtablet moet stadig in die mond opgelos word.

Hoeveel LOZEZIL® word gegee

Verwyder een suigtablet uit die foelie stulpverpakking. Plaas suigtablet in die mond sodat dit stadig kan oplos. Los een suigtablet stadig elke 2 – 3 uur in die mond op. Moenie 12 suigtablette in enige 24-uur periode oorskry nie

As jy meer LOZEZIL® neem as wat jy moet:

Jy kan maag ongemak ervaar. Moenie meer van hierdie produk neem nie. In die geval van oordosis, raadpleeg jou dokter of apteker. Indien nie een beskikbaar is nie, kontak die naaste hospitaal of gifsentrum.

As jy vergeet om LOZEZIL® te neem

Moenie 'n dubbeldosis neem om vergete individuele dosisse in te haal nie.

4. Moontlike newe-effekte

LOZEZIL® kan newe-effekte hê.

Nie alle newe-effekte wat vir LOZEZIL® aangemeld is, is in hierdie pamflet ingesluit nie. Indien u algemene gesondheid vererger of as u enige nadelige effekte ervaar terwyl u hierdie medisyne ontvang, raadpleeg asseblief u dokter, apteker of ander gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, hou op om LOZEZIL® te gebruik en vertel jou dokter dadelik of gaan na die ongevalle-afdeling by jou naaste hospitaal:

As jy enige hipersensitiewiteit vir hierdie produk ervaar, dit wil sê moeilike asemhaling, swelling van die gesig, nek, tong of keel en uitslag (ernstige allergiese reaksies).

Indien enige van hierdie newe-effekte ernstig word, vertel asseblief jou dokter of apteker.

Vertel jou dokter as jy enige van die volgende opmerk:

Newe-effekte – frekwensie nie bekend nie

- Jeuk, brandende sensasie of pyn in die tong
 - Seer of ongemaklike gevoel in die mondarea
- Indien u enige newe-effekte opmerk wat nie in hierdie pamflet genoem word nie, stel asseblief u dokter of apteker in kennis.

Aanmelding van newe-effekte

As jy newe-effekte kry, praat met jou dokter, apteker of verpleegster. Jy kan ook newe-effekte aan SAHPRA rapporteer via die "6.04 Adverse Drug Reaction Reporting Form", wat aanlyn gevind word onder SAHPRA se publikasies: <https://www.sahpra.org.za/Publications/Index/8>. Deur newe-effekte aan te meld, kan jy help om meer inligting oor die veiligheid van LOZEZIL® te verskaf.

5. Hoe om LOZEZIL® te bewaar

Bewaar alle medisyne buite bereik van kinders. Bewaar teen of benede 25 °C. Bewaar in die oorspronklike verpakking.

6. Inhoud van die pakkie en ander inligting

Wat bevat LOZEZIL®

Die aktiewe bestanddele is: 1,2 mg 2,4-dichloorbensielalkohol en 0,6 mg amielmetakresol

Die ander bestanddele is:

Vir Swartbessie-suigtablette:

Sukrose, Vloeibare glukose, Sitroensuurmonohidraat, Mentha-olie, Swartbessiegeur, Kleur Ponceau 4R, Kleur Swart PN.

Vir Heuning Suurlemoen suigtablette:

Sukrose, vloeibare glukose, Mentha-olie, heuninggeur, essensie suurlemoenolie, karamel, kleur Ponceau 4R, riboflavenfosfaatnatrium.

Vir Suurlemoen-suigtablette:

Sukrose, vloeibare glukose, sitroensuurmonohidraat, mentha-olie, suurlemoenoliekonsentraat, anysolie, riboflavenfosfaatnatrium.

Vir Lemoen suigtablette:

Sukrose, Vloeibare glukose, Sitroensuurmonohidraat, Mentha-olie, Lemoen-olie soet uitstekend, Anysolie, Riboflavenfosfaatnatrium, Kleur Ponceau 4R.

Hoe lyk LOZEZIL® en inhoud van die verpakking

Silwer ondeursigtige aluminium en helder deursigtige PVC/PE/PVDC foelie stulpverpakking, met 12 suigtablette per stulpstrokie en 24 suigtablette verpak in 'n buitekarton saam met pamflet.

Houer van Sertifikaat van Registrasie

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Die pamflet is laas hersien op:

30 Augustus 2022

Registrasienuommer(s)

LOZEZIL® BLACKCURRANT: 50/16.4/2301
LOZEZIL® HONEY LEMON: 50/16.4/2331
LOZEZIL® LEMON: 50/16.4/2316
LOZEZIL® ORANGE: 50/16.4/2311