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 use 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 use LOZEZIL
3. How to use 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 use LOZEZIL

Do not use 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 use 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 you 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 use LOZEZIL

Do not take a double dose to make up for forgotten indivual 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 using 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 substances 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

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LOZEZIL HONEY LEMON: 50/16.4/2331
LOZEZIL LEMON: 50/16.4/2316
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