

Applicant:	Biotech Laboratories (Pty) Ltd	1.3.2 Approved Patient Information Leaflet
Dosage form:	Lozenge	
Strength:	Each lozenge contains 0,6 mg amylmetacresol and 1,2 mg 2,4-dichlorobenzyl alcohol	

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S0

ZEPTALOZ Blackcurrant

ZEPTALOZ Honey Lemon

ZEPTALOZ Lemon

ZEPTALOZ 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.

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

- Keep this leaflet. You may need to read it again.
- Do not share ZEPTALOZ 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 ZEPTALOZ is and what it is used for
2. What you need to know before you use ZEPTALOZ
3. How to use ZEPTALOZ
4. Possible side effects
5. How to store ZEPTALOZ
6. Contents of the pack and other information

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1. What ZEPTALOZ is and what it is used for

ZEPTALOZ 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 ZEPTALOZ

Do not use ZEPTALOZ 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 ZEPTALOZ.

Other medicines and ZEPTALOZ

Always tell your healthcare provider if you are taking any other medicine. (This includes all

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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 ZEPTALOZ 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 ZEPTALOZ affects them.

ZEPTALOZ 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 ZEPTALOZ.

3. How to use ZEPTALOZ

Do not share medicines prescribed for you with any other person

Always use ZEPTALOZ 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 ZEPTALOZ is given

Lozenge are to be dissolved in mouth, slowly.

How much ZEPTALOZ is given

Remove one lozenge from the foil blister packaging.

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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 ZEPTALOZ 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 ZEPTALOZ

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

4. Possible side effects

ZEPTALOZ can have side effects.

Not all side effects reported for ZEPTALOZ 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 ZEPTALOZ 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

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- 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 ZEPTALOZ.

5. How to store ZEPTALOZ

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 ZEPTALOZ contains

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

The other ingredients are:

For ZEPTALOZ Blackcurrant:

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

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For ZEPTALOZ Honey Lemon:

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

For ZEPTALOZ Lemon:

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

For ZEPTALOZ Orange:

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

What ZEPTALOZ 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
Ground Floor Block K West Central Park
400 16th Road, Randjespark
Halfway House
Midrand 1685
Tel. nr: 011 848 3050

The leaflet was last revised in

To be allocated on approval.

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