SCHEDULING STATUS S0

1. NAME OF THE MEDICINAL PRODUCT

ZEPTALOZ Blackcurrant

ZEPTALOZ Honey Lemon

ZEPTALOZ Lemon

ZEPTALOZ Orange

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each Lozenge contains:

Amylmetacresol	0,6 mg
2,4-Dichlorobenzyl Alcohol	1,2 mg

Excipients with known effect:

Contains sugar.

Each lozenge contains 1618,0 mg sucrose and 1038,0 mg liquid glucose.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lozenge

Description of ZEPTALOZ Blackcurrant:

Violet coloured round biconvex lozenges (with occasional presence of air bubbles entrapped in the lozenges and rough edges).

Description of ZEPTALOZ Honey Lemon:

Brownish yellow coloured round biconvex lozenges (with occasional presence of air bubbles entrapped in the lozenges and rough edges).

Description of ZEPTALOZ Lemon:

Yellow coloured round biconvex lozenges (with occasional presence of air bubbles entrapped in the lozenges and rough edges).

Description of ZEPTALOZ Orange:

Orange coloured round biconvex lozenges (with occasional presence of air bubbles entrapped in the lozenges and rough edges).

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

Posology

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.

Elderly

There is no need for dosage reduction in the elderly.

Paediatric population

ZEPTALOZ is not suitable for children under 6 years (see section 4.3)

Method of administration

For oral administration

To be dissolved slowly in the mouth

4.3 Contraindications

- Hypersensitivity to 2,4-dichlorobenzyl alcohol, amylmetacresol or to any of the excipients in ZEPTALOZ (see section 6.1)
- Children under 6 years of age

4.4 Special warnings and precautions for use

When a sore throat persists for more than two days, consult your doctor.

Excipient warning

ZEPTALOZ contains glucose and sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrose-isomaltose insufficiency should not take ZEPTALOZ.

Paediatric population

Not to be given to children under 6 years (see section 4.3).

Remember young children can choke on lozenges.

4.5 Interaction with other medicines and other forms of interaction

No clinically significant interactions are known.

4.6 Fertility, pregnancy and lactation

Pregnancy

There are no or limited amount of data from the use of amylmetacresol and 2,4-dichlorbenzyl alcohol in pregnancy.

Care should be taken when using this product in pregnancy and medical advice sought if necessary.

Breastfeeding

It is unknown whether 2,4-dichlorobenzyl alcohol, amylmetacresol or metabolites are excreted in human milk. A risk to the newborns / infants cannot be excluded.

Fertility

No data available

4.7 Effects on ability to drive and use machines

ZEPTALOZ has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Immune System Disorders

Frequency unknown: Hypersensitivity[ab1]

Gastrointestinal Disorders

Frequency unknown: Glossodynia[ab], oral discomfort[ab]

[a]2,4-dichlorobenzyl alcohol,

[b]amylmetacresol

[1] Hypersensitivity reactions may include rash, urticaria and angioedema, which may include swelling of the face, neck, throat or tongue that could affect breathing.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare 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

Overdosage should not present a problem other than gastrointestinal discomfort. Treatment should be symptomatic.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Throat Preparations; Antiseptics

Category and class: A 16.4 Naso-pharyngeal and bucco-pharyngeal antiseptics

ATC Code: R02AA03

Mechanism of action:

ZEPTALOZ has disinfectant and antiseptic properties.

5.2 Pharmacokinetic properties

None available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

For ZEPTALOZ Blackcurrant:

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

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.

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store at or below 25 °C.

Store in the original package.

6.5 Nature and contents of container

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.

6.6 Special precautions for disposal and other handling

Not applicable.

7. 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

8. REGISTRATION NUMBER(S)

ZEPTALOZ Blackcurrant – 57/16.4/0679.678

ZEPTALOZ Honey Lemon – 57/16.4/0681.680

ZEPTALOZ Lemon – 57/16.4/0683.682

ZEPTALOZ Orange – 57/16.4/0685.684

10. DATE OF REVISION OF THE TEXT

29 August 2023