

|              |                                                                                   |                                           |
|--------------|-----------------------------------------------------------------------------------|-------------------------------------------|
| Applicant:   | Biotech Laboratories (Pty) Ltd                                                    | 1.3.1.1 Approved Professional Information |
| Dosage form: | Lozenge                                                                           |                                           |
| Strength:    | Each lozenge contains 0,6 mg amylmetacresol and 1,2 mg 2,4-dichlorobenzyl alcohol |                                           |

## SCHEDULING STATUS S0

### 1. NAME OF THE MEDICINAL PRODUCT

THROATSIL Blackcurrant

THROATSIL Honey Lemon

THROATSIL Lemon

THROATSIL 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 THROATSIL Blackcurrant:

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

Description of THROATSIL Honey Lemon:

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

Description of THROATSIL Lemon:

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

Description of THROATSIL 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**

THROATSIL: 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**

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THROATSIL 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 THROATSIL (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**

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

### **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**

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There are no or limited amount of data from the use of amylmetacresol and 2,4-dichlorobenzyl 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**

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

### **4.8 Undesirable effects**

#### **Immune System Disorders**

*Frequency unknown:* Hypersensitivity<sup>ab1</sup>

#### **Gastrointestinal Disorders**

*Frequency unknown:* Glossodynia<sup>ab</sup>, oral discomfort<sup>ab</sup>

<sup>a</sup>2,4-dichlorobenzyl alcohol,

<sup>b</sup>amylmetacresol

<sup>1</sup> 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*

|              |                                                                                   |                                           |
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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:

THROATSIL has disinfectant and antiseptic properties.

#### **5.2 Pharmacokinetic properties**

None available.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

For THROATSIL Blackcurrant:

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

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For THROATSIL Honey Lemon:

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

For THROATSIL Lemon:

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

For THROATSIL 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.

|              |                                                                                   |                                           |
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## **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)**

THROATSIL Blackcurrant – 57/16.4/0678

THROATSIL Honey Lemon – 57/16.4/0680

THROATSIL Lemon – 57/16.4/0682

THROATSIL Orange – 57/16.4/0684

## **10. DATE OF REVISION OF THE TEXT**

29 August 2023