SCHEDULING STATUS:

S0

PROPRIETARY NAME: **CEPACOL® THROAT LOZENGES MENTHOL**

CEPACOL® THROAT LOZENGES REGULAR

CEPACOL® THROAT LOZENGES BLACKCURRANT FLAVOUR

CEPACOL® THROAT LOZENGES HONEY AND LEMON FLAVOUR

(AND DOSAGE FORM) **(LOZENGES)**

COMPOSITION:

Each lozenge contains:

Cetylpyridinium chloride	1,47 mg
Benzyl alcohol	6,5 mg
Contains sugar: Liquid glucose	1,08 g
Sucrose	1,17 g

List of excipients Eucalyptol, liquid glucose, menthol, sucrose.

The Regular, Blackcurrant, Menthol and Honey and Lemon variants contain approved and flavours and colourants.

PHARMACOLOGICAL CLASSIFICATION:

A 16.4 Naso-pharyngeal and bucco-pharyngeal antiseptics

PHARMACOLOGICAL ACTION:

Pharmacodynamic properties:

Cetylpyridinium chloride is a quaternary pyridinium antiseptic compound which has bactericidal and fungicidal activity. *In vitro*, cetylpyridinium chloride has shown antibacterial activity against Gram-positive cocci such as *Streptococccus pyogenes, Streptococcus viridans* and *Staphylococcus aureus* normally associated with mouth and throat infections.

Diluted benzyl alcohol possesses weak local anaesthetic activity.

Pharmacokinetic properties:

Benzyl alcohol is metabolised to benzoic acid. The benzoic acid is conjugated with glycine in the liver to form hippuric acid, which is excreted in the urine.

INDICATIONS:

For the symptomatic relief of sore throat.

CONTRAINDICATIONS:

Hypersensitivity to cetylpyridinium chloride, benzyl alcohol or any of the ingredients of CEPACOL THROAT LOZENGES.

Not suitable for diabetics.

Not for use by children under three years of age.

WARNINGS AND SPECIAL PRECAUTIONS

Severe sore throat or sore throat accompanied by high fever or headache or nausea and vomiting, or any sore throat persisting for more than two days, may be serious. In such cases, consult your doctor.

Pregnancy and lactation:

Safety in pregnancy and lactation has not been established.

DOSAGE AND DIRECTIONS FOR USE:

Dissolve lozenge slowly in the mouth. Use as needed.

SIDE EFFECTS

Immune system disorders:

Benzyl alcohol and menthol: Hypersensitivity reactions

Nervous system disorders:

Cetylpyridium, benzylalcohol, menthol and eucalyptol: central nervous system depression, headache, vertigo, drowsiness, convulsions, ataxia, hypotension and coma.

Respiratory, thoracic and mediastinal disorders:

Cetylpyridium chloride: Depolarising muscle relaxation and toxic symptoms including dyspnea and cyanosis due to paralysis of the respiratory muscles, possibly leading to asphyxia.

Gastrointestinal disorders:

Cetylpyridium chloride, benzylalcohol, menthol and eucalyptol: Nausea, vomiting, diarrhoea, severe abdominal pain.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Treatment is symptomatic and supportive.

Overdosage of benzyl alcohol can cause nausea, vomiting, diarrhoea, headache, vertigo, and CNS depression.

IDENTIFICATION:

CEPACOL THROAT LOZENGES REGULAR: Round, yellow, hard candy lozenge embossed with the symbol "+" on both sides.

CEPACOL THROAT LOZENGES MENTHOL: Round, colourless, opaque, hard candy lozenge embossed with the symbol "+" on both sides.

CEPACOL THROAT LOZENGES BLACKCURRANT FLAVOUR: Round, maroon, hard candy lozenge embossed with the symbol "+" on both sides.

CEPACOL THROAT LOZENGES HONEY AND LEMON FLAVOUR: Round, honey-yellow, hard candy lozenge embossed with the symbol "+" on both sides.

PRESENTATION:

Packs of 8 or 24 lozenges in clear PVC/PVDC aluminium foil blister packs.

STORAGE INSTRUCTIONS:

Store in a cool, dry place at or below 25 ºC.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE/ REGISTRATION NUMBER:

CEPACOL THROAT LOZENGES REGULAR: H 1388 (Act 101 of 1965)

Namibia: 14/16.3/0389 – NS0

Botswana: B9316110 – S4

CEPACOL THROAT LOZENGES MENTHOL: A40/16.4/0297

Namibia: 14/16.3/0388 – NS0

Botswana: B9316110 – S4

CEPACOL THROAT LOZENGES BLACKCURRANT FLAVOUR: 33/16.4/0492

Namibia: 05/16.3/0143 – NS0

Botswana: B9316110 – S4

CEPACOL THROAT LOZENGES HONEY AND LEMON FLAVOUR: 33/16.4/0505

Namibia: 05/16.4/0144 – NS0

Botswana: B9316110 – S4

NAME AND BUSINESS ADDRESS OF APPLICANT/HOLDER OF REGISTRATION CERTIFICATE:

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DATE OF PUBLICATION OF THIS PACKAGE INSERT:

2 October 2014