SCHEDULING STATUS: **S0**

PROPRIETARY NAME: **CEPACOL ANTIBACTERIAL THROAT GARGLE**

(AND DOSAGE FORM) **(SOLUTION)**

COMPOSITION:

Each 100 ml solution contains:

Cetylpyridinium chloride	50 mg (1:2 000)
Alcohol	15,8 % v/v
Disodium edetate (antioxidant)	1,0 mg

Sugar free

Contains TARTRAZINE

Excipients: Sodium phosphate dried, sodium dihydrogen phosphate, saccharin, polysorbate 80, glycerine, methyl salicylate, eucalyptol, cinnamon oil imitation, peppermint oil-special, menthol, purified water

PHARMACOLOGICAL CLASSIFICATION:

A 16.4 Naso-pharyngeal and bucco-pharyngeal antiseptics

PHARMACOLOGICAL ACTION:

The active ingredient of **CEPACOL ANTIBACTERIAL THROAT GARGLE** is cetylpyridinium chloride, a quarternary ammonium compound which, in laboratory tests, has rapid and prolonged bactericidal and fungicidal activity. Cetylpyridinium chloride was found to be bactericidal in low concentrations against a

wide variety of Gram-positive and Gram-negative bacteria which included haemolytic *Streptococcus*, *Staphylococcus aureus*, *Escherichia coli* and *Lactobacillus acidophilus*. Fungicidal action has been demonstrated against *Monilia albicans*, the cause of oral thrush.

INDICATIONS:

For quick symptomatic relief and topical antibacterial effects in sore throat (excluding tonsillitis) due to colds and in minor mouth infections. For quick symptomatic relief of throat irritation and tickling cough due to dust, allergy, smoke or excessive use of the voice and discomfort following periodontal procedures and minor surgery of the mouth. **CEPACOL ANTIBACTERIAL THROAT GARGLE** is recommended for daily oral hygiene and in dentistry for rinsing the operative field during dental prophylaxis and before taking impressions.

CONTRAINDICATIONS:

None known.

WARNINGS AND SPECIAL PRECAUTIONS:

This product contains tartrazine which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of tartrazine sensitivity in the general population is currently thought to be low it is frequently seen in patients who also have aspirin sensitivity.

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 a doctor.

DOSAGE AND DIRECTIONS FOR USE:

Gargle / Mouthwash: May be used full strength or diluted with an equal volume of water, warm if desired, as often as necessary.

SIDE EFFECTS:

No untoward effects have been reported with this preparation.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

No cases of overdosage have been reported.

IDENTIFICATION:

Clear yellow solution.

PRESENTATION:

Bottles of 200 ml.

STORAGE INSTRUCTIONS:

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN.

REFERENCE NUMBER:

H 1387 (Act 101/1965).

Namibia: Application Number: 03 1002589 NS0

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