

PROPRIETARY NAME (AND DOSAGE FORM):

Listerine Cool Mint Mouthwash (Solution).

COMPOSITION:

Per 20 ml:

Thymol 12,780 mg

Alcohol (95 %) v/v 4,530 ml

Other Ingredients: Benzoic Acid, Eucalyptol, FD & C Green No. 3 (C.I. 42053), L-Menthol, Mint Flavour N&A SNO 11397, Methyl Salicylate, Menthol, Poloxamer 407, Sodium Benzoate, Saccharin Sodium, Sorbitol Solution.

PHARMACOLOGICAL CLASSIFICATION:

A: 16.4 Naso-bucco-pharyngeal antiseptics.

PHARMACOLOGICAL ACTION:

Bacteriostatic antiseptic.

INDICATIONS:

Mild infections of the mouth and throat and associated bad breath. Gingivitis and the control of plaque.

CONTRA-INDICATIONS:

Sensitivity to any of the ingredients. Do not administer to children.

DOSAGE AND DIRECTIONS FOR USE:

Use 20 ml (approximately $\frac{3}{4}$ capful); rinse the teeth and gums and gargle for 15 -30 seconds twice daily as an adjunct to usual oral hygiene. Do not swallow.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

None observed.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

If large quantities are swallowed the toxic effects include:

Thymol:

Extensive local corrosion, with pain, nausea, vomiting, sweating, and diarrhoea.

Alcohol:

Depression of cortical function causing loss of judgement, emotional lability, muscle inco-ordination, visual impairment, slurred speech, and ataxia. Hangover effects may include nausea, headache, dizziness, and tremor.

Treatment:

Contact a doctor. Empty the stomach by aspiration and lavage. Haemodialysis is of value in severe alcoholic poisoning.

Castor oil or olive oil may be added to the water to dissolve thymol and delay absorption; 50 ml of oil may be left in the stomach. Keep the patient warm and treat pulmonary oedema, systemic acidosis, respiratory failure, and circulatory failure symptomatically. Respiration may have to be assisted. Haemodialysis is of value in severe alcoholic poisoning.

IDENTIFICATION:

A brilliantly clear, blue-green, aromatic solution.

PRESENTATION:

Bottles of 250 ml and 500 ml.

STORAGE INSTRUCTIONS:

Store in a cool (at or below 25 °C) place, away from direct sunlight.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER:

South Africa: 28/16.4/0332

Botswana: R9700044

Ghana: FDB.SD 133-1056

Kenya: H99/168

Malawi: PMPB/PL353/9 GSL

Namibia: 05/16.4/0289

Nigeria: NAFDAC Reg. No.: 04-4671

Tanzania: TAN 05,062 D08A WAR

Zambia: 082/031 GS

Zimbabwe: 96/20.3.4/3044

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF
REGISTRATION:**

Johnson & Johnson West Africa Limited,
Ground Floor Landmark Towers. 5B Water Cooperation Road, Onuru V.I. Annex,
Lagos State.

Manufacturer

Johnson & Johnson (Pty) Ltd.

241 Main Road

Retreat

7945

South Africa