Professional information for TEETH AND GUM DEFENCE LISTERINE

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

Teeth and Gum Defence Listerine® solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 20 mL liquid contains:

Thymol	12,780 mg
Alcohol (95 %)	4,540 mL
Sodium fluoride	4,420 mg

Excipients with known effect:

Contains sodium benzoate (E211) and benzoic acid (E210).

Contains sweeteners: Each 20 mL contains 23,4 mg saccharin sodium and 4 g sorbitol solution.

Sugar free.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Mouthwash.

A brilliantly clear green solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Mild infections of the mouth and throat and associated bad breath. Gingivitis and the control of plaque. To strengthen teeth, increasing resistance to acid attack, demineralisation and dental caries.

4.2 Posology and method of administration

Adults and children 12 years and over:

Use 20 mL (approximately ¾ capful) full strength; rinse the teeth and gums and gargle for 30 seconds twice daily as an adjunct to usual oral hygiene. **Do not swallow.** Do not eat or drink for 30 minutes after rinsing.

Children:

Do not administer to children under 12 years of age.

4.3 Contraindications

Hypersensitivity to sodium fluoride, alcohol, thymol, or to any of the other ingredients of Teeth and Gum Defence Listerine® (see section 6.1).

Do not administer to children under 12 years of age.

4.4 Special warnings and precautions for use

Since Teeth and Gum Defence Listerine® contains alcohol, it should be used with caution in patients with Sjogren's syndrome, dry mouth, and burning mouth syndrome.

Stop use and consult a dentist if oral irritation or any new symptoms develop.

Teeth and Gum Defence Listerine® contains sodium benzoate and benzoic acid

Teeth and Gum Defence Listerine® may cause non-immunologic immediate contact reactions by a possible cholinergic mechanism.

4.5 Interaction with other medicines and other forms of interaction

There are no known interactions.

4.6 Fertility, pregnancy and lactation

Safety has not been established in pregnancy and lactation. Teeth and Gum Defence Listerine® is intended as a mouthwash, it is therefore unlikely that the use will present a risk to the pregnant woman or foetus when used as directed.

Sodium fluoride is excreted in human breast milk when taken orally. The recommended use of Teeth and Gum Defence Listerine® solution entails using only small volumes of product, therefore it would be expected that only minimal amounts of the product will be swallowed. It is therefore unlikely that use of sodium fluoride will present a risk to the pregnant woman or foetus when used in recommended dosages and used as directed.

4.7 Effects on ability to drive and use machines

Teeth and Gum Defence Listerine® is unlikely to have an effect on the ability to drive a vehicle or use machines. Caution is advised before driving a vehicle or operating machinery until the effects of Teeth and Gum Defence Listerine® are known.

4.8 Undesirable effects

Adverse drug reactions (ADRs) identified during post-marketing experience are included below.

Immune system disorders

Hypersensitivity reactions (including anaphylactic reactions, angioedema, pruritus and urticaria)

Nervous system disorders

Ageusia, dysgeusia, headache

Respiratory, thoracic and mediastinal disorders

Sneezing

Gastrointestinal disorders

Abdominal discomfort, diarrhoea, nausea, vomiting, salivary gland enlargement

Skin and subcutaneous tissue disorders

Rash

General disorders and administration site conditions

Application site reactions, such as oral discomfort and pain, discolouration, burning sensation, oral mucosal exfoliation and blistering, dry mouth, stomatitis, throat irritation, swelling, tongue disorders (including swollen tongue, tongue blistering and glossodynia/glossitis), lip disorders (including cheilitis, dry and chapped lips and lip pain).

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of Teeth and Gum Defence Listerine® is important. It allows continued monitoring of the benefit/risk balance of Teeth and Gum Defence Listerine®. Health care 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

For further information, please contact the Johnson & Johnson call centre on 0860 410032 (landline).

4.9 Overdose

Teeth and Gum Defence Listerine® solution is intended for use as a mouthwash and should not be swallowed. Oral ingestion may be associated with gastrointestinal symptoms such as epigastric pain, nausea and vomiting and symptoms of central nervous system (CNS) depression.

Ingestion of sufficient quantities may lead to signs/symptoms of alcohol intoxication and/or significant metabolic disturbances.

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 incoordination, visual impairment, slurred speech, and ataxia. Hangover effects may include nausea, headache, dizziness and tremor.

Sodium fluoride

In acute poisoning, sodium fluoride taken by mouth is corrosive forming hydrofluoric acid in the stomach.

Excessive salivation and tearing, nausea, burning or cramp-like abdominal pain, vomiting and diarrhoea are frequent.

Sodium fluoride may produce metabolic and electrolyte disturbances, including hypocalcaemia. Systemic effects include tremors, hyperreflexia, paraesthesia, tetany, convulsions, cardiac failure, lethargy, fatigue, weakness, pallor, paralysis of muscles of swallowing, carpo-pedal spams or spasms of the extremities, disorientation as well as low blood pressure, arrhythmia, respiratory depression, coma. Death was reported after ingestion. Chronic overdose with fluoride-containing oral care products or use in conjunction with other sources of fluoride (e.g. supplementation as

fluoridated water or salt) may result in dental fluorosis in children less than 6 years.

Treatment

Contact a doctor, poison control centre or emergency clinic. Empty the stomach by aspiration. 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 alcohol poisoning.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Bacteriostatic antiseptic.

Sodium fluoride

Fluoride promotes remineralisation of decalcified enamel and reduces dental plaque bacteria. Deposits of fluoride ion in the enamel surface of teeth increase resistance to acid and to development of caries.

Thymol

Thymol helps to prevent and reduce supragingival plaque biofilm accumulation by inhibiting the proliferation of plaque forming bacteria that contribute to the development of gingivitis.
Thymol also inhibits the growth of Gram-negative microorganisms that are most likely responsible for bad breath.

Alcohol 95 %

Alcohol is extensively used as a solvent and preservative in pharmaceutical preparations. It is bacteriostatic at low concentrations but has bactericidal activity at higher concentrations, with some fungicidal and virucidal activity.

Alcohol also has anhidrotic, rubefacient, astringent and haemostatic properties.

5.2 Pharmacokinetic properties

The pharmacokinetics of the combined ingredients, in the concentrations utilised, have not been investigated. The extent of absorption from the buccal mucosa is unknown. There are no related literature studies on the pharmacokinetics of the combined ingredients for topical use.

5.3 Preclinical safety data

Preclinical data reveal no special hazard for humans based on conventional studies of single and repeated dose toxicity, genotoxicity, carcinogenicity and toxicity to reproduction and development.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzoic acid (E210),

D&C Yellow (colourant),

eucalyptol (flavourant),

FD&C Green (colourant),

L-menthol,

menthol,

methyl salicylate (flavourant),

mouthwash flavour terpeneless,

poloxamer,

purified water,

saccharin sodium (E954),

sodium benzoate (E211),

sorbitol solution (E420).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store at or below 25 °C, away from direct sunlight.

Store in a cool place.

KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

Teeth and Gum Defence Listerine® is packed in 250 mL and 500 mL transparent polyethylene terephthalate (PET) bottles with black polypropylene (PP) child-resistant caps.

6.6 Special precautions for disposal and other handling

None.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Johnson & Johnson (Pty) Ltd.

241 Main Road

Retreat

7945

South Africa

8. REGISTRATION NUMBER

38/16.4/0021

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1 December 2006.

10. DATE OF REVISION OF THE TEXT

26 June 2021

EXPORT REGISTRATION DETAILS:

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Namibia: 13/16.4/0156 NS0

Nigeria: NAFDAC Reg. No. B4-6501

Tanzania: TZ 14 H 0147

Zambia: 082/059 GS