SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
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Loftus Park
2nd Floor
Kirkness Road
Arcadia
0083

***Enquiries*: Nokukhanya.ncube@sahpra.org.za**
***Sequence no/reference no*: 34/16.4/0294**

The Responsible Pharmacist
JOHNSON & JOHNSON (PTY) LTD
PRIVATE BAG X6
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SOUTH AFRICA
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Clinical approval date	10/11/2021
Applicant's cover letter date	08/09/2021
Final recommendation date	23/08/2021
Proprietary name(s) (including duplicates)	Tartar Control Listerine Antiseptic
API(s)	Alcohol 95 %; Thymol; Zinc chloride
Registration number(s)	34/16.4/0294

Dear Sir/Madam,

Kindly be informed that the Authority has completed the evaluation of the above-mentioned Professional Information (PI) and Patient Information Leaflet (PIL) variation application submitted on the 08/09/2021

1. The amendments to the PI and the PIL are approved.
2. The attached PI and PIL be accepted as the currently approved PI and PIL
3. The date of revision reflected on the PI and the PIL should be: 23/08/2021
4. The final, dated version of the above PI and PIL must be submitted to SAHPRA via email to pipilrepository@sahpra.org.za within 5 working days.

Yours Faithfully,

L.DHLAMINI
MANAGER: CLINICAL POST-REGISTRATION UNIT

Professional information for TARTAR CONTROL LISTERINE® ANTISEPTIC

SCHEDULING STATUS

S0

1. NAME OF THE MEDICINE

Tartar Control Listerine® Antiseptic solution

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 20 mL:

Thymol	12,78 mg
Alcohol (95 %) *v/v*	4,54 mL
Zinc chloride	18,00 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 clear blue solution with a mild peppermint odour and flavour, which may become cloudy in cold weather.

4. CLINICAL PARTICULARS

Sign: _____

4.1 Therapeutic indications

Mild infections of the mouth and throat and associated bad breath. Gingivitis and the control of plaque. Prevention of tartar build-up.

4.2 Posology and method of administration

For 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.

Cold weather may cloud Tartar Control Listerine® Antiseptic; its antiseptic properties are not affected.

Not recommended for children under 12 years of age.

4.3 Contraindications

- Hypersensitivity to thymol, alcohol or to any of the other ingredients in Tartar Control Listerine® Antiseptic (see section 6.1).
- Do not administer to children under 12 years of age.

4.4 Special warnings and precautions for use

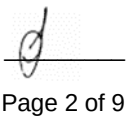
Do not swallow (see section 4.9).

Keep out of reach of children.

If swallowed, patients should get medical help or contact a Poison Control Centre right away.

Since Tartar Control Listerine® Antiseptic contains alcohol, this should be used with caution in patients with Sjogren's syndrome, dry mouth or burning mouth syndrome.

Patients should stop use and ask a dentist if oral irritation or any new symptoms develop.

Sign: 

Tartar Control Listerine® Antiseptic contains sodium benzoate and benzoic acid

Tartar Control Listerine® Antiseptic may cause non-immunologic immediate contact reactions by a possible cholinergic mechanism.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There are no adequate and well-controlled studies in pregnant women.

However, because with recommended use only small volumes of Tartar Control Listerine® Antiseptic would be expected to be swallowed, it is considered unlikely that the recommended use of Tartar Control Listerine® Antiseptic will present a risk to the pregnant woman or foetus.

It is not known whether Tartar Control Listerine® Antiseptic is excreted in human breast milk. However, because with recommended use only small volumes Tartar Control Listerine® Antiseptic would be expected to be swallowed, it is considered unlikely that the recommended use of Tartar Control Listerine® Antiseptic will present a risk to the infant.

4.7 Effects on ability to drive and use machines

Tartar Control Listerine® Antiseptic is unlikely to affect the ability to drive and use machinery. Caution is advised before driving a vehicle or operating machinery until the effects of Tartar Control Listerine® Antiseptic are known.

4.8 Undesirable effects

Adverse reactions identified during post-marketing experience:

Immune system disorders:

Frequency unknown: hypersensitivity reactions (including anaphylactic reactions, angioedema, and urticaria)

Nervous system disorders:

Frequency unknown ageusia, dysgeusia, headache

Respiratory, thoracic and mediastinal disorders:

Frequency unknown sneezing

Gastrointestinal disorders:

Frequency unknown abdominal discomfort, diarrhoea, nausea, vomiting, salivary gland enlargement

Skin and subcutaneous tissue disorders:

Frequency unknown rash

General disorders and administration site disorders:

Frequency unknown application site reactions (usually these consist of dry mouth, tingling or burning pain but sometimes can include bleeding, blisters, discolouration, swelling and ulceration)

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of Tartar Control Listerine® Antiseptic is important. It allows continued monitoring of the benefit/risk balance of Tartar Control Listerine®

Antiseptic. 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

Tartar Control Listerine® Antiseptic is intended for use as a mouthwash and should not be swallowed.

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.

Zinc chloride:

Gastrointestinal corrosion.

Treatment:

Empty the stomach by aspiration, taking care to avoid perforation. 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Bacteriostatic antiseptic.

Thymol helps prevent and reduce supragingival plaque biofilm accumulation by inhibiting the proliferation of plaque forming bacteria that contribute to the development of gingivitis.

Thymol inhibits the growth of gram-negative microorganisms that produce volatile sulphur compounds that are most likely responsible for bad breath.

5.2 Pharmacokinetic properties

The pharmacokinetics of thymol in the concentrations utilised, has not been investigated. The extent of absorption from the buccal mucosa is unknown.

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)

Eucalyptol (flavourant)

FD & C Blue No. 1 (colourant)

L- menthol (flavourant)

Menthol

Methyl salicylate (flavourant)

Mint flavour

Poloxamer

Purified water

Saccharin sodium (E954)

Sodium benzoate (E211)

Sorbitol solution (E420).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

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

Store in a cool place.

6.5 Nature and contents of container

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

Sign: _____

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Johnson & Johnson (Pty) Ltd.

241 Main Road

Retreat

7945

South Africa

8. REGISTRATION NUMBER

34/16.4/0294

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

08 May 2000.

10. DATE OF REVISION OF THE TEXT

To be allocated by SAHPRA.

EXPORT REGISTRATION DETAILS

Botswana: BOT 04 00726

Kenya: H2008/18738/187

Namibia: 04/16.4/1527 NS0

Sign: _____

Nigeria: NAFDAC Reg. No: A4-3866

Uganda: 6018/15/07

Zambia: 082/053 GS

Sign: _____

TARTAR CONTROL LISTERINE® ANTISEPTIC

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S0

Tartar Control Listerine® Antiseptic solution

Thymol, alcohol and zinc chloride.

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

Sugar free.

Read all of this leaflet carefully because it contains important information for you.

Tartar Control Listerine® Antiseptic is available without a doctor's prescription, for you to treat a mild condition. Nevertheless, you still need to use Tartar Control Listerine® Antiseptic carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see a doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What Tartar Control Listerine® Antiseptic is and what it is used for

Tartar Control Listerine® Antiseptic belongs to a class of medicines used to treat mild mouth and throat infections as a mouthwash.

Use Tartar Control Listerine® Antiseptic for:

- Mild infections of the mouth and throat and associated bad breath.
- Gingivitis (gum disease) and to control plaque.
- Prevents tartar build-up.

2. What you need to know before you use Tartar Control Listerine® Antiseptic

Do not use Tartar Control Listerine® Antiseptic:

- If you are hypersensitive (allergic) to thymol, alcohol or any of the other ingredients of Tartar Control Listerine® Antiseptic (see **What Tartar Control Listerine® Antiseptic contains**).
- In children under the age of 12 years.

Warnings and precautions

Take special care with Tartar Control Listerine® Antiseptic:

- Since Tartar Control Listerine® Antiseptic contains alcohol, use it with caution if you have Sjogren's syndrome (immune system disorder which causes dry mouth and dry eyes), dry mouth, or burning mouth syndrome. If you are unsure, do not use Tartar Control Listerine® Antiseptic before talking to your doctor, dentist or pharmacist.
- If you experience any irritation in your mouth or any new symptoms develop while you are using Tartar Control Listerine® Antiseptic, stop using Tartar Control Listerine® Antiseptic and ask your dentist for advice.

Children and adolescents

Tartar Control Listerine® Antiseptic should not be used in children under the age of 12 years.

Other medicines and Tartar Control Listerine® Antiseptic

There are no known interactions between Tartar Control Listerine® Antiseptic and other medicines.

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking Tartar Control Listerine® Antiseptic.

Tartar Control Listerine® Antiseptic is intended for use as mouthwash, it is therefore unlikely that using it while pregnant will harm you or your baby if you use it as directed.

Driving and using machines

Tartar Control Listerine® Antiseptic is unlikely to have an effect on your ability to drive a vehicle or use machines. Caution is advised before driving a vehicle or operating machinery until you know how Tartar Control Listerine® Antiseptic affects you.

Tartar Control Listerine® Antiseptic contains sodium benzoate and benzoic acid

Tartar Control Listerine® Antiseptic may cause local irritation.

3. How to use Tartar Control Listerine® Antiseptic

Do not share medicines with any other person. Always take exactly as instructed. You should check with your health care provider if you are unsure.

Use Tartar Control Listerine® Antiseptic as part of your usual oral hygiene regimen.

For adults and children over 12 years:

Use 20 mL (approximately ¾ capful). Rinse the teeth and gums and gargle for 30 seconds twice daily.

Do not swallow Tartar Control Listerine® Antiseptic.

If you have the impression that the effect of Tartar Control Listerine® Antiseptic is too strong or too weak, tell your doctor or pharmacist.

If you take more Tartar Control Listerine® Antiseptic than you should

Tartar Control Listerine® Antiseptic is intended for use as a mouthwash and should not be swallowed. If you swallow large quantities, you may experience the following overdose effects: stomach pain, nausea, vomiting, diarrhoea, sweating, headache, dizziness, tremor (shaking), loss of judgement, uncontrollable changes in your mood, uncoordinated movement or loss of balance, changes in your eyesight, slurred speech, a lack of muscle control or corrosive damage to your gut.

Do not use more than the stated dose.

In the event of an overdosage or if you or your child accidently swallow a large quantity, consult your doctor or pharmacist. If neither is available contact the nearest hospital or poison centre.

Take this leaflet and the rest of the remaining Tartar Control Listerine® Antiseptic with you so the doctor will know what you have taken.

4. Possible side effects

Tartar Control Listerine® Antiseptic can have side effects.

Not all side effects reported for Tartar Control Listerine® Antiseptic are included in this leaflet.

Should your general health worsen or if you experience any untoward effects while using Tartar Control Listerine® Antiseptic, please consult your health care provider for advice.

If any of the following happens, stop using Tartar Control Listerine® Antiseptic and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to Tartar Control Listerine® Antiseptic. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice any of the following:

Side effects occurring with an unknown frequency:

- loss of taste or altered taste,
- headache,
- sneezing,
- abdominal (stomach) discomfort, diarrhoea, nausea, vomiting or enlargement of your salivary glands,
- application site reactions, such as dry mouth, tingling or burning pain, bleeding, blistering, discolouration, swelling or ulceration.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or

pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.

By reporting side effects, you can help provide more information on the safety of Tartar Control Listerine® Antiseptic.

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

5. How to store Tartar Control Listerine® Antiseptic

- Store at or below 25 °C, away from direct sunlight.
- Store in a cool place.
- Keep in the original container until required for use.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the container.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains and sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What Tartar Control Listerine® Antiseptic contains

Each 20 mL contains:

Thymol	12,78 mg
Alcohol (95 %)	4,54 mL

Sign: _____

Zinc chloride 18,00 mg

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

The other ingredients are eucalyptol (flavourant), FD & C Blue No. 1 (colourant), L- menthol (flavourant), menthol, methyl salicylate (flavourant), mint flavour, poloxamer, purified water, saccharin sodium (E954), sorbitol solution (E420).

What Tartar Control Listerine® Antiseptic looks like and contents of the pack

A clear blue solution with a mild peppermint odour and flavour, which may become cloudy in cold weather.

Tartar Control Listerine® Antiseptic is packed in 250 mL and 500 mL 750 mL transparent polyethylene terephthalate (PET) bottles with black polypropylene (PP) child-resistant caps.

Holder of certificate of registration

Johnson & Johnson (Pty) Ltd

241 Main Road

Retreat

7945

South Africa

This leaflet was last revised in

To be allocated by SAHPRA.

Registration number

34/16.4/0294

Sign: _____

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Zambia: 082/053 GS

Sign: _____