PROFESSIONAL INFORMATION FOR

DERMADINE ORAL ANTISEPTIC

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

DERMADINE ORAL ANTISEPTIC (solution)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 ml of DERMADINE ORAL ANTISEPTIC contains:

Povidone-Iodine 1,00 g (1 % *m/v*) equivalent to 0,1 % *m/v* available iodine.

Contains Alcohol 8,85 % *v/v*

Contains sweetener: Saccharin Sodium 0,07 g

For the full list of excipients, see **section 6.1**

3. PHARMACEUTICAL FORM

Solution.

DERMADINE ORAL ANTISEPTIC is a dark brown clear liquid.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DERMADINE ORAL ANTISEPTIC is recommended for relief of painful infections and inflammatory conditions of the mouth and pharynx and as a routine mouthwash.

Infections:

Aphthous ulcers, gingivitis, stomatitis and pharyngitis due to superficial infections. It is also recommended for use prophylactically during and after oral surgery.

4.2 Posology and method of administration

DERMADINE ORAL ANTISEPTIC should not be swallowed.

As a mouthwash:

Dilute one part of DERMADINE ORAL ANTISEPTIC with two parts of water, rinse mouth thoroughly and spit out, or use as directed by doctor or dentist.

For infections of mouth and throat:

Use full strength and rinse or gargle for thirty seconds then spit out, repeat hourly, or as directed by doctor or dentist.

Paediatric population

For children under 3 years:

Dilute one part DERMADINE ORAL ANTISEPTIC with three parts water and paint the mouth with the aid of a cotton bud.

4.3 Contraindications

DERMADINE ORAL ANTISEPTIC is contraindicated in:

- patients with known hypersensitivity to povidone-iodine or to any of the excipients used in the formulation of DERMADINE ORAL ANTISEPTIC (see **section 6.1**)**.**
- patients with non-toxic nodular colloid goitre should not use povidone-iodine.
- pregnant or lactating women.
- patients with hyperfunction of the thyroid (hyperthyroidism), other manifested thyroid diseases (thyroid disorder) should not use povidone-Iodine.

4.4 Special warnings and precautions for use

Certain individuals may become sensitized to povidone-iodine.

If irritation, swelling or redness occurs, discontinue treatment and consult your doctor. If severe or persistent sore throat, or sore throat accompanied by high fever, headache, nausea and vomiting occur, consult your doctor promptly as these symptoms may indicate a serious condition. Absorption of povidone-iodine may interfere with thyroid function tests. Regular or prolonged use should be avoided in patients with thyroid disorders.

4.5 Interaction with other medicinal products and other forms of interaction

Absorption of iodine from DERMADINE ORAL ANTISEPTIC may interfere with thyroid function tests and can make a planned treatment of the thyroid with iodine (radioiodine therapy) impossible. After the end of the treatment an appropriate interval should be allowed before a new scintigram is carried out. Regular or prolonged use should be avoided in patients receiving concomitant lithium therapy.

4.6 Fertility, pregnancy and lactation

Pregnancy:

Not to be used in pregnancy.

Breastfeeding:

Not to be used during breastfeeding.

4.7 Effects on ability to drive and use machines

The effects on ability to drive and use machines has not been established.

4.8 Undesirable effects

System Organ Class	Frequency unknown
Nervous system disorders	Headache
Gastrointestinal disorders	Nausea, vomiting
Skin and subcutaneous tissue disorders	Hypersensitivity and local irritation may occur, for example urticaria, pruritus, erythema, small blisters, angioedema, or similar manifestations.
General disorders and administration site conditions	Irritation, swelling, redness
Investigations	Interference with thyroid function tests.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Health care providers are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website, or to Cipla Medpro (Pty) Ltd. by email: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free).

4.9 Overdose

Should ingestion occur, systemic effects such as metabolic acidosis, hypernatraemia and renal impairment may occur. Symptoms of acute poisoning are a disagreeable metallic

taste, vomiting, abdominal pain and diarrhoea. Anuria may occur 1 to 3 days later; death may be due to circulatory failure, oedema of the glottis resulting in asphyxia, aspiration pneumonia or pulmonary oedema.

Oesophageal stricture may occur if the patient survives the acute stage.

For treatment of acute poisoning, supply patient with draughts of milk and starch mucilage.

A doctor should be consulted without delay. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

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

Pharmacotherapeutic group: antiseptic and disinfectant

ATC code: D08AG02

Povidone-iodine is a multivalent broad-spectrum local disinfectant having bactericidal and fungicidal properties. The effect on vegetative cells of various bacteria and fungi is due to the liberation of free iodine from the complex.

Many viruses, protozoa, yeasts, cysts and spores are also susceptible.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Ethanol 96 %
- Citric Acid-Phosphate Buffer
- Purified water
- Polyethylene Glycol 400
- Saccharin sodium

6.2 Incompatibilities

No applicable.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

DERMADINE ORAL ANTISEPTIC is packed in bottles of 200 ml and 2,5 litre.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

Return all unused or expired medicines to your pharmacist for safe disposal. Do not dispose of unused medicines in drains or sewage systems (e.g. toilets)

7. HOLDER OF CERTIFICATE OF REGISTRATION

CIPLA MEDPRO (PTY) LTD.

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Parc du Cap

Mispel Street

Bellville

7530

Customer Care: 080 222 6662

8. REGISTRATION NUMBER(S)

H 1511 (Act 101/1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

12 February 1975

10. DATE OF REVISION OF THE TEXT

10 February 2026

Namibia:
NS011/14.1/0175