PROFESSIONAL INFORMATION FOR

DERMADINE ANTISEPTIC OINTMENT

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

DERMADINE ANTISEPTIC OINTMENT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 25 g contains 2,5 g Povidone-iodine which is equivalent to 1% of available iodine, in a water miscible base.

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

3. PHARMACEUTICAL FORM

A smooth, amber coloured ointment with a characteristic iodine odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

DERMADINE ANTISEPTIC OINTMENT is used as a general antiseptic in the treatment of skin infections, wounds, cuts abrasions, burns if not extensive, bedsores and for post-operative wounds.

4.2 Posology and method of administration

Posology

The affected area should be cleaned and dried. Apply to affected areas twice daily or as directed. An occlusive dressing may be used if necessary.

4.3 Contraindications

DERMADINE ANTISEPTIC OINTMENT is contraindicated in:

- Patients with known hypersensitivity to povidone-iodine or to any of the excipients used in the formulation of DERMADINE ANTISEPTIC OINTMENT (see **section 6.1**).
- Application to large areas of broken skin (e.g. severe and extensive burns) should be avoided as excessive absorption of iodine may occur.
- Not to be used during pregnancy or by lactating women.
- Povidone-iodine should not be used on patients with non-toxic nodular colloid goitre.

4.4 Special warnings and precautions for use

Not to be used by persons allergic to iodine.

Hypersensitivity reactions and local irritation may occur. However, if irritation, swelling, or redness occur, discontinue treatment and consult your physician. Hypothyroidism may occur after topical application to neonates. Absorption of povidone-iodine may interfere with thyroid function tests.

NOTE: Stains on synthetic fabrics may be removed by washing and rinsing in dilute ammonia.

4.5 Interaction with other medicinal products and other forms of interaction

Use with concurrent lithium therapy has been shown to exhibit additive hypothyroidic effects. Absorption of iodine from povidone-iodine through either intact skin or broken skin may interfere with thyroid function tests. Contamination with povidone-iodine of several types of tests for the detection of occult blood in faeces or blood in urine may produce false-positive results.

4.6 Fertility, pregnancy and lactation

Pregnancy:

Not to be used during 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
Endocrine disorders	Hypothyroidism may occur after topical application to neonates.
General disorders and administration site conditions	Hypersensitivity and local irritation, swelling, redness
Investigations	Absorption of povidone-iodine may interfere with thyroid function tests.

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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 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 and to Cipla Medpro (Pty) Ltd at drugsafetysa@cipla.com or telephone 080 222 6662 (toll free).

4.9 Overdose

Systemic effects including metabolic acidosis, hypernatraemia and renal impairment may follow the application of povidone-iodine to severe burns or large areas otherwise denuded of skin. Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

A 14.1 Wound disinfectants.

Pharmacotherapeutic group: antiseptic and disinfectant.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

- Polyethylene Glycol 400
- Polyethylene Glycol 4000
- Sodium hydroxide solution
- Purified water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months

6.4 Special precautions for storage

- Store at or below 25 °C.
- Keep tightly closed.

6.5 Nature and contents of container

DERMADINE ANTISPETIC OINTMENT is packed in 25g and 50g tubes and 500g jars.

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.1049 (Act 101 /1965)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

N/A (Old medicine)

10. DATE OF REVISION OF THE TEXT

10 February 2023

Namibia: NS0 11/16.4/0176