Professional Information

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

SEPTADINE® ANTISEPTIC OINTMENT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 g contains 1 g Povidone-Iodine in a water miscible base.

Available iodine: 250 mg/25 g of ointment.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Ointment

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

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

SEPTADINE® ANTISEPTIC OINTMENT is used as an antiseptic in the treatment of skin infections, decubitus ulcers, wounds, cuts, abrasions, burns and for post-operative wounds.

4.2 Posology and method of administration

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

- Hypersensitivity to Povidone-Iodine, or to any of the excipients in listed in section 6.1.
- Application to large areas of broken skin (eg. 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

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 medicines 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

Not to be used during pregnancy or by lactating women.

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	Local 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 asked to report any suspected adverse reactions to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8

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

Category and class: A.14.1 Wound disinfectants

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

- Polyethylene glycol 400
- Polyethylene glycol 4000
- Purified water
- Sodium hydroxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store at or below 25 ^{0}C. Keep tightly closed.

6.5 Nature and contents of container

25 g tubes, 50 g tubes and 500 g jars.

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

Ranbaxy Pharmaceuticals (Pty) Ltd

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8. REGISTRATION NUMBERS

28/14.1/ 0651 (S.A)

(S3)BOT 0500772 (Botswana)
04/14.1/1005 (Namibia)
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9. DATE OF FIRST AUTHORISATION

20 October 1995

10. DATE OF REVISION OF THE TEXT

24 August 2022