SCHEDULING STATUS

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1. NAME OF THE MEDICINE

SEPTISOOTH ANTISEPTIC GEL

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 1 g of the gel contains: Povidone iodine 100 mg.

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Gel

An amber coloured gel with a characteristic odour of iodine.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

SEPTISOOTH ANTISEPTIC GEL is a general antiseptic in the treatment of:

- Skin infections.
- Decubitus ulcers.
- Wounds, cuts and abrasions.
- Burns.
- Postoperative wounds.

4.2 Posology and method of administration

Posology

FOR EXTERNAL USE ONLY.

Apply SEPTISOOTH ANTISEPTIC GEL liberally to the cleaned and dried affected area.

Cover with a dressing or bandage if required.

4.3 Contraindications

- Hypersensitivity to the povidone iodine, iodine or to any of the excipients listed in section 6.1.
- Patients with non-toxic nodular colloid goitre or on neonates.
- Pregnancy and lactation (see section 4.6).

Application to large areas of broken skin should be avoided as excessive absorption of iodine may occur.

4.4 Special warnings and precautions for use

Hypersensitivity

Hypersensitivity reactions and local irritation may occur. However, treatment should be discontinued if irritation, swelling or redness occur.

Systemic absorption

Povidone iodine as in SEPTISOOTH ANTISEPTIC GEL can be absorbed systemically during the topical treatment of burns and large areas of broken skin. The degree of absorption is proportional to the depth and extent of the burn or broken skin.

Prolonged treatment with povidone iodine of patients with severe and extensive burns may cause metabolic acidosis, hypernatraemia and renal impairment. In patients at risk SEPTISOOTH ANTISEPTIC GEL should be used with caution.

Renal insufficiency, neonates and infants

Special caution is needed in patients with pre-existing renal insufficiency and in neonates and infants up to 6 months of age. In such cases monitoring of thyroid function should be considered.

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

4.5 Interactions with other medicines and other forms of interaction

- Lithium: Use with concurrent lithium therapy has been shown to increase the risk of (transient) hypothyroidism.
- Laboratory tests: 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.
- Other disinfectants and/or antiseptics: Do not mix or co-administer with disinfectants and/or antiseptics or other medicines used for the treatment of wounds.

4.6 Fertility, pregnancy and lactation

Safety and efficacy during pregnancy and lactation have not been established. Pregnant and women who are breastfeeding should not use SEPTISOOTH ANTISEPTIC GEL (see section 4.3).

4.7 Effects on ability to drive and use machines

SEPTISOOTH ANTISEPTIC GEL has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

a. Tabulated summary of adverse reactions

System Organ Class	**Frequency**	**Adverse reactions**
Immune system disorders	Less frequent	Hypersensitivity, anaphylactic reaction
Endocrine disorders	Less frequent	Hyperthyroidism
Metabolism and nutrition disorders	Frequency unknown	Metabolic acidosis, hypernatraemia

System Organ Class	Frequency	Adverse reactions
Skin and subcutaneous tissue disorders	Less frequent	Urticaria, angioedema, cutaneous haemorrhage, purpura
Renal and urinary disorders	Frequency unknown	Renal impairment
General disorders and administrative site conditions	Frequency unknown	Local irritation, swelling, redness*
Investigations	Frequency unknown	Interference with thyroid function tests

b. Description of selected adverse reactions

** Skin reactions*

Povidone iodine may produce local skin reactions although it is considered to be less irritant than iodine.

Iodine associated effects

Severe burns or too large areas otherwise denuded of skin may produce the systemic effects associated with iodine which may include metabolic acidosis, hypernatraemia and renal impairment.

c. Paediatric population

Hypothyroidism may occur after topical application to neonates.

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. Healthcare professionals 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

With normal topical application, iodine absorption is so low that the risk of overdose can be virtually excluded.

If ingested, the povidone iodine contained in SEPTISOOTH ANTISEPTIC GEL is unlikely to have any toxic effects.

Iodine ingested in large amounts can produce goitre and hypothyroidism as well as hyperthyroidism and may lead to a range of adverse effects, often called iodism, such as metallic taste, vomiting, abdominal pain or bloody diarrhoea, although some of the effects may be due to hypersensitivity.

Treatment

In severe cases, treat with sodium thiosulphate 1 – 5 % as a specific antidote. Gastric irritation can be reduced with milk.

Monitoring of the fluid and electrolyte balance could be useful.

High serum iodine levels resulting from excessive use can be reduced by haemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacological classification: A13.1 Antiseptics, Disinfectants, Cleansing agents.

Pharmacotherapeutic group: Antiseptic and disinfectant

ATC code: D08AG02

Povidone iodine is an iodophor[~~e~~] which are loose complexes of iodine with carrier polymers. It is a multivalent broad spectrum local antiseptic and exerts an effect against bacteria, fungi, viruses, protozoa, cysts and spores due to the gradual release of the iodine form the base.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid

Disodium phosphate

Poloxamer 407

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 in a dry place.

6.5 Nature and contents of container

White polyethylene tubes with a white polypropylene cap containing 25 g and

white polyethylene jars with polypropylene lids containing 500 g gel.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

PHARMACORP (PTY) LTD

29 Victoria Link

Route 21 Corporate Park

Irene, 0178

South Africa

8. REGISTRATION NUMBER

29/13.1/0738

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

18 April 2006

10. DATE OF REVISION OF THE TEXT: 25 June 2023