Professional Information

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

SEPTADINE® ORAL ANTISEPTIC (SOLUTION)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 ml contains: Povidone-Iodine 1,00 g (1 % *m/v*) equivalent to 0,1 % *m/v* available iodine.

Contains 8,5 % *v/v* alcohol

Sugar free, artificially sweetened.

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution

SEPTADINE® ORAL ANTISEPTIC is a clear dark-brown aqueous solution with a characteristic iodine smell, and a pleasant flavour.

4. CLINICAL PARTICULARS

4.1. Therapeutic indications

SEPTADINE® ORAL ANTISEPTIC is recommended for relief of painful infections and inflammatory conditions of the mouth and pharynx, and as a routine mouthwash. Aphthous ulcers, gingivitis, stomatitis and pharyngitis due to superficial infections. Prophylaxis during and after oral surgery.

4.2 Posology and method of administration

As a mouthwash: Dilute one part of **SEPTADINE® ORAL ANTISEPTIC** with two parts of water, rinse mouth thoroughly and spit out, or use as directed by physician or dentist.

For infections of mouth and throat: Use full strength and rinse or gargle for 30 seconds then spit out, repeat hourly, or as directed by physician or dentist.

For children under 3 years: Dilute one part **SEPTADINE® ORAL ANTISEPTIC** with three parts water and paint the mouth with the aid of a cotton-bud.

4.3 Contraindications

- Hypersensitivity to Povidone-Iodine, or to any of the excipients in listed in section 6.1.
- Patients with non-toxic nodular colloid goiter should not use Povidone-Iodine.
- Not to be used in pregnancy or by 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 physician. If severe or persistent sore throat, or sore throat accompanied by high fever, headache, nausea and vomiting occur, consult your physician 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 medicines and other forms of interaction

Absorption of iodine from **SEPTADINE® ORAL ANTISEPTIC** may interfere with thyroid function tests and can make a planned treatment of the thyroid with iodine (radioidone

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

Not to be used in 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**
Nervous system disorders	Headache
Gastrointestinal disorders	Nausea, vomiting
General disorders and administration site conditions	irritation, swelling, redness
Skin and subcutaneous tissue disorders	Hypersensitivity and local irritation may occur, for example urticaria, pruritus, erythema, small blisters, angioedema, or similar manifestations.
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

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.

Lavage may be attempted if there is no oesophageal damage.

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

5. PHARMACOLOGICAL PROPERTIES

Category and class: A 16.4 Naso-,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

- Anhydrous disodium hydrogen phosphate

- Citric acid anhydrous
- Ethanol
- Polyethylene glycol 400
- Purified water
- Saccharin sodium

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 Months

6.4 Special precautions for storage

Store at or below 25 ^{o}C and protect from light.

6.5 Nature and contents of container

Bottles of 200 ml and 2,5 litres

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

14 Lautre Road

Stormill Ext. 1

Roodepoort

1724

South Africa

8. REGISTRATION NUMBERS

28/16.4/0650 (S.A.)

NSO 04/16.4/1620 (Namibia) 200ml

GS 168/016(Zambia) 200 ml

9. DATE OF FIRST AUTHORISATION

19 January 1995

10. DATE OF REVISION OF THE TEXT

24 August 2022