Professional Information for Medicines for Human Use

SCHEDULING STATUS

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1. NAME OF MEDICINE

POVIDONE IODINE SCRUB B. BRAUN (LIQUID)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 mL of POVIDONE IODINE SCRUB B. BRAUN contains 7,5 g of Povidone Iodine equal to 0,75 g of available iodine.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Liquid

A deep brown coloured foaming liquid having the characteristic odour of iodine.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

As a surgical scrub for degerming the hands prior to surgical procedure and pre-operative preparation of the patient's skin. POVIDONE IODINE SCRUB B. BRAUN may be used to advantage on the patient's skin following the use of the scrub. Effective as an antiseptic wash in infected skin conditions and a general germicidal cleanser in consulting rooms.

4.2 Posology and method of administration

POVIDONE IODINE SCRUB B. BRAUN should be used undiluted.

4.3 Contraindications

Sensitivity to Povidone Iodine or other Iodine containing products.

Hypersensitivity to iodine, polyvinylpyrrolidone or to any excipient. History of abnormal thyroid function or goitre (in particular nodular colloid goitre, endemic goitre and Hashimoto's thyroiditis).

Use in children under two years of age.

Regular use should be avoided in patients on concurrent lithium therapy.

4.4 Special warnings and precautions for use

Not to be used by persons allergic to iodine.

Use of this preparation may interfere with tests of thyroid function. Iodine is absorbed through burns and broken skin and to a lesser extent through intact skin and may lead to toxic levels of iodine in the blood, particularly in patients with renal insufficiency. If symptoms occur, suggesting changes in thyroid function, these should be monitored. If local irritation and hypersensitivity develop, then discontinue treatment.

Hypothyroidism can result from topical application of Povidone Iodine to neonates. Severe metabolic acidosis may occur in patients suffering from burns greater than 20 % of the body surface. The use of Povidone Iodine in such cases should be discontinued.

It may permanently discolour white gold jewellery and it is recommended that this type of jewellery be removed before using Povidone Iodine Scrub B. Braun

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

Fertility

No data available

Pregnancy

Iodine freely crosses the placenta and is secreted in breast milk. Thyroid function disorders have been reported in the offspring of mothers exposed to pharmacological doses of iodine.

4.7 Effects on ability to drive and use machines

None stated

4.8 Undesirable effects

Local irritation, skin burns, and sensitivity reactions have been reported rarely. Anaphylactic reactions, anaphylactoid reactions

and anaphylactic shock have been reported uncommonly with products containing povidone-iodine or povidone.

Excess iodine can produce goitre and hypothyroidism or hyperthyroidism. Such effects have occasionally been seen with extensive or prolonged use of povidone iodine. Other effects that have been reported are metabolic acidosis and acute renal failure.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to SAHPRA via the '**6.04 Adverse Drug Reactions Reporting Form**'. Found under SAHPRA's publications: https://www/sahpra.org.za/Publications/Index/8.

4.9 Overdose

Symptoms and treatment

The symptoms of acute poisoning from ingestion of iodine are mainly due to its corrosive effects on the gastro-intestinal tract. A disagreeable metallic taste, vomiting, abdominal pain and diarrhoea may occur. If the stomach contains starch the vomit is coloured blue. Anuria may occur one to three days later, or death may be due to circulatory failure, oedema of the glottis resulting in asphyxia or pulmonary oedema. The fatal dose is usually 2 – 3 g. The prognosis is generally favourable. Treatment is symptomatic and supportive.

Deliberate or accidental ingestion of large quantities of povidone iodine will result in high blood concentrations of iodine and gastrointestinal corrosive effects including vomiting, diarrhoea and abdominal pain. Systemic toxicity may result in shock, hypotension, tachycardia, fever, metabolic acidosis and renal impairment. Symptomatic and supportive treatment should be started with special attention to monitoring electrolyte balance, renal function, thyroid function and liver function. Haemodialysis effectively clears iodine and should be employed in severe cases of iodine poisoning particularly if renal failure is present. Continuous venovenous haemodiafiltration is less effective than haemodialysis.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Povidone Iodine is an iodofore which slowly liberates inorganic iodine in contact with the skin and mucous membranes. Iodine is microbiocidal against most bacteria, fungi, protozoa, viruses, and yeasts.

13.1 Antiseptics, disinfectants, cleansing agents

ATC Code: D08AG02

5.2: Pharmacokinetic properties

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Trisodium phosphate

Citric Acid

Glycerine

Hydroxyethylcellulose (Natrasol)

SLES (Sodium Laureth Sulphate)

Purified Water

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store in airtight containers in a cool, dry place, at or below 25°C and protect from light.

6.5 Nature and contents of container

Stored in HDPE plastic containers, 50 mL, 500 mL with cap, 500 mL with pump and 1L with cap.

6.6 Special precautions for disposal of a used medicine or waste materials derived from such medicine and other handling of the product

No special requirements.

7. NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

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8. REGISTRATION NUMBER

U/13.1/66

9. DATE OF FIRST AUTHORISATION

21 January 1983

10. DATE OF REVISION OF TEXT

10 February 2023