

1. NAME OF THE MEDICINAL PRODUCT

WOSAN SOLUTION 2.5 % (Povidone Iodine Solution 2.5 % w/v)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Povidone Iodine2.5 %

w/v Purified Water. Q.s.

3. PHARMACEUTICAL FORM

Topical solution

A dark brown colored solution with characteristic smell of iodine

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For External Use Only

As disinfectant and antiseptic for the treatment of contaminated wounds pre-operative preparation of the skin, mucous membranes as well as disinfection of equipment

4.2 Posology and method of administration

Route of administration: Topical use.

Gently apply on the disinfected skin area twice a day after cleaning up the wound

4.3 Contraindications

Regular or prolonged use should be avoided in patients with thyroid disorders or those receiving lithium therapies.

4.4 Special warnings and precautions for use

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 used for long periods thyroid function tests should be performed. Particular care should be taken when treating patients with excessive burns. Use of this preparation

In patients with renal impairment may possibly result in the development of toxic levels of iodine" Therefore, iodine levels should be monitored in these patients.

Particular care should also be taken when treating neonates and very low birth weight infants. Povidone iodine Surgical Scrub can permanently discolor white gold jewelry and it is recommended that this type of jewelry should be removed before using Povidone iodine Solution. Avoid contact with eyes. In case of contact with the eyes, immediately flush the eyes liberally with water for at least 15 minutes and seek medical attention. If easy to do, remove contact lenses.

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 Pregnancy and Lactation

No report exists on the topical use to establish any adverse effect to pregnant or nursing mothers.

4.7 Effects on ability to drive and use machines

Not Applicable

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.

4.9 Overdose

Not likely

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Wosan solution 2.5 % contains povidone-iodine, a complex of iodine which shows all the broad spectrum germicidal activity of elemental iodine.

5.2 Pharmacokinetic properties

Not Applicable

5.3 Preclinical safety data

Not Applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glycerin

Citric acid

Dibasic sodium Phosphate

Xanthan gum

Potassium Iodate

6.2 Incompatibilities

None

6.3 Shelf life

3 years

6.4 Special precautions for storage

Store below 30°C

Protect from direct sunlight.

Keep all medicines out of the reach of children

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

2L white HDPE jar with induction sealing cap

6.6 Special precautions for disposal <and other handling>

Not Applicable

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