

PROFESSIONAL INFORMATION

SCHEDULING STATUS S0

1 NAME OF THE MEDICINE

BETADINE® SURGICAL SCRUB 7,5 % w/v (Solution)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 100 ml of BETADINE® SURGICAL SCRUB contains 7,5 g povidone-iodine (7,5 % w/v).

For full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous Solution (Scrub)

For topical administration.

Reddish-brown, viscous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

An antiseptic for the pre-procedural and post-procedural treatment of the skin.

4.2 Posology and method of administration

Posology

Paediatric population

BETADINE® SURGICAL SCRUB is contraindicated in children below the age of 2 years (see section 4.3).

Apply for a maximum of 14 consecutive days up to 5 ml up to twice a day for adults and once a day for children aged 2 years or older.

Rinse off with water after application.

Method of administration

For topical administration only. NOT FOR ORAL USE.

Apply up to 5 ml for surgical handwashing and for pre-operative scrubbing. Rinse off under running water.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Thyroid dysfunction or goitre (in particular nodular colloid goitre, endemic goitre and Hashimoto's thyroiditis).
- During radioiodine scintigraphy or radioiodine treatment of thyroid diseases.
- Products containing mercury, should not be used concomitantly due to formation of a substance which can damage the skin.
- Children below the age of 2 years.
- Patients on concurrent lithium therapy.

4.4 Special warnings and precautions for use

In pre-operative preparation, avoid pooling beneath the patient. Prolonged exposure to wet solution may cause irritation or rarely, severe skin reactions. Chemical burns of skin due to pooling may occur.

In instances of skin irritation, contact dermatitis or hypersensitivity, discontinue use.

Do not heat prior to application.

Povidone iodine use could lead to transient skin discolouration at the application site.

It may permanently discolour white gold jewellery and it is recommended that this type of jewellery be removed before using BETADINE® SURGICAL SCRUB.

For external use only.

Paediatric population

BETADINE® SURGICAL SCRUB should not be used in children under 2 years of age and its application in children (2 years or above) must be performed by an adult.

4.5 Interaction with other medicines and other forms of interaction

The PVP-iodine complex is effective at pH values of between 2.0 and 7.0. It has to be expected that the complex will react with protein and other unsaturated organic compounds, leading to impairment of its effectiveness.

The concomitant use of wound-treatment preparations containing enzymatic components leads to a weakening of the effects of both substances.

Products containing silver, hydrogen peroxide, and taurolidine may interact with povidone-iodine.

Povidone iodine products when used concomitantly or immediately after application of octenidine containing antiseptics in the same or adjacent sites may lead to transient dark discolouration in the areas involved.

Due to the oxidative effect of povidone-iodine preparations various diagnostic agents can show false-positive lab results (e.g., tests with toluidine or gum guaiac for the determination of haemoglobin or glucose in the stool or the urine). Absorption of iodine from povidone-iodine products may lower the iodine uptake of the thyroid. This can lead to interference with various investigations (thyroid scintigraphy, determination of protein-bound iodine (PBI), radioiodine diagnostics) and can interfere with treatment of the thyroid with iodine (radioiodine therapy).

After the end of the treatment, an appropriate interval should be allowed before a new scintigram is carried out.

4.6 Fertility, pregnancy and lactation

Povidone-iodine passes into the placenta and is secreted in breast milk. Thyroid function disorders including congenital hypothyroidism have been reported in the offspring of mothers who have received iodine.

Povidone-iodine use should be avoided.

Fertility

No data is available.

4.7 Effects on ability to drive and use machines

BETADINE® SURGICAL SCRUB has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Immune system disorders

Less frequent: Hypersensitivity, anaphylactic reaction

Endocrine disorders

Less frequent: Hyperthyroidism (sometimes with symptoms such as tachycardia or restlessness) *

Frequency unknown: Hypothyroidism ***

Metabolism and nutrition disorders

Frequency unknown: Electrolyte imbalance **, metabolic acidosis **

Skin and subcutaneous tissue disorders

Less frequent: Contact dermatitis (with symptoms such as erythema, small blisters and pruritus), angioedema

Renal and urinary disorders

Frequency unknown: Acute renal failure**, Blood osmolarity abnormal **

Injury, poisoning and procedural complications

Frequency unknown: Chemical burn of skin ****

* In patients with a history of thyroid disease (see Section 4.4) following a notable uptake of iodine e.g. following long term use of povidone–iodine solution for the treatment of wounds and burns over extensive areas of the skin

** May occur following uptake of large amounts of povidone-iodine (e.g. in the treatment of burns)

*** Hypothyroidism following prolonged or extensive use of povidone iodine

**** May occur due to “pooling” beneath the patient in pre- operative preparation

Reporting 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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. Alternatively report to: ZADrugSafety@mundipharma.co.za

4.9 Overdose

Systemic toxicity may result in renal impairment (including anuria), metabolic acidosis, acute respiratory distress and congestive heart failure.

In the case of deliberate or accidental ingestion of large quantities of povidone-iodine the following may manifest: oesophagitis, gastritis, chemical pulmonary oedema, transient hyperthyroidism, haemolytic anaemia, acute tubular necrosis and several acid-base disturbances.

Hyperthyroidism or hypothyroidism may also develop.

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

A.13.1 Antiseptics, disinfectants and cleansing agents

5.1 Pharmacodynamic properties

Povidone iodine is a complex of iodine (the active moiety) and the synthetic polymer povidone, (PVP), which acts as a sustained release reservoir of iodine (PVP does not have any intrinsic antibacterial activity) and also enables easier contact of iodine to cell membranes. As povidone iodine comes in contact with the skin and mucous membranes, iodine dissociates from the povidone iodine polymer complex; it is the free iodine that rapidly causes microbicidal activity, whereas iodine bound to the polymer serves as an iodine reservoir. This gradual release of iodine reduces the drawbacks associated with the presence of elemental iodine and maintains its highly effective microbicidal activity. The free iodine rapidly penetrates microorganisms and attacks the key groups of proteins, amino acids, nucleotides and unsaturated fatty acids. It reacts with thiol, sulfhydryl and hydroxyl groups of the amino acids in the enzymes and structural proteins of the microorganisms thereby oxidising them.

Povidone iodine is a broad-spectrum antimicrobial agent; its antimicrobial effects have been demonstrated *in vitro* against several different microorganisms including numerous strains of bacteria (gram-negative and gram-positive and acid fast), viruses (enveloped and non-enveloped), yeasts, moulds, fungi and protozoa.

5.2 Pharmacokinetic properties

Absorption, Distribution, Metabolism and Elimination

Iodine

Following dissociation of iodine from povidone, the skin absorbs iodine and the amount absorbed is dependent on the type of skin (e.g., healthy or damaged) and also on the duration and the surface area of the application.

Absorbed iodine/iodide is distributed throughout the body via the circulatory system. A portion (approximately 30 %) is removed by the thyroid for hormonal synthesis. Iodine is also distributed (despite to a minor extent) to different organs including liver. Iodine crosses the placenta and is excreted in breast milk.

Iodine is reduced to iodide and is concentrated from the blood stream into the thyroid follicular cell through the action of the sodium/iodide symporter (NIS). The thyroid-stimulating hormone (TSH) stimulates iodide transport from the blood into thyroid cells, oxidation of iodide to iodine, and iodine binding to tyrosine.

Iodine, unless utilised in the thyroid, is excreted mainly via urine

Povidone

Povidone does not pass the blood brain barrier or cross the placenta and is not excreted in the milk.

The metabolism of povidone is minimal (< 0, 3 %).

The excretion of povidone is mainly via urine and also via bile.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric Acid Monohydrate, Coco Glucoside, Disodium Phosphate, Glycerol, Hydroxyethyl Cellulose, Potassium Iodate, Sodium Hydroxide, Sodium Laureth Sulfate, Purified Water.

6.2 Incompatibilities

Povidone-iodine should not be used together with silver, hydrogen peroxide and taurolidine.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Store at or below 25 °C.

6.5 Nature and contents of container

High-density polyethylene (HDPE) container with low-density polyethylene (LDPE) inserts fitted with HDPE caps.

Pack sizes: 120 ml, 500 ml and 1000 ml

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

N/A

7 HOLDER OF CERTIFICATE OF REGISTRATION

Mundipharma (Pty) Ltd
Block D, Grosvenor Square
Park Lane, Century City
Cape Town, 7441
South Africa

8 REGISTRATION NUMBER

57/13.1/0272

9 DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

8 April 2025

10 DATE OF REVISION OF THE TEXT

N/A

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