

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Betadine Surgical Scrub 7.5%

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Povidone-Iodine USP 7.5% w/v

(available iodine 0.75% w/v)

Purified water q.s

3. PHARMACEUTICAL FORM

Cleansing Solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the Pre- and post-operative scrubbing or washing, pre- and post-operative use on patients, general use in physician's office.

4.2 Posology and method of administration

Route of administration: Topical administration.

A. For Preoperative Washing by operating Personnel.

B. For Preoperative Use on Patients

C. Use in physician clinic

A. For Preoperative Washing by operating Personnel

1. Wet hands and forearms with water. Pour about 5ml. of scrub on the palm of the hand and spread over both hands and forearms. Without adding more water, rub the scrub thoroughly over all the areas for about 5 minutes. Use a soft brush if desired. Clean thoroughly under fingernails. Add a little water and develop copious suds. Rinse thoroughly under running water.

2. Complete the wash by scrubbing with another 5 ml. of scrub in the same way.

B. For Preoperative Use on Patients

After the skin area is shaved, wet it with water. Apply scrub (1 ml. is sufficient to cover an area of 125-130 cm²), develop lather and scrub thoroughly for about five minutes. Rinse off by aid of sterile gauze saturated with water. The area may then be painted with Betadine Standardised Microbicidal Solution 5% or 10% and allowed to dry.

C. Use in physician office

Use for washing whenever a germicidal soap is required.

4.3 Contraindications

Not to be used in known hypersensitivity to iodine or povidone. Not to be used in hyperfunction of the thyroid (hyperthyroidism), other manifest thyroid diseases, as well as before and after radioactive iodine therapy. It should not be used prior to radioiodine scintigraphy or radioiodine treatment of thyroid carcinoma.

4.4 Special warnings and precautions for use

For topical use only. In pre-operative preparation, avoid “pooling” beneath the patient. Prolonged exposure to wet scrub may cause irritation or rarely, severe skin reactions. In instances of skin irritation or contact dermatitis or hypersensitivity, discontinue use. Keep out of the reach of children.

Preparations containing povidone-iodine may permanently stain rhodium-plated white gold. They may also temporarily discolor some precious metals in which case any discoloration can readily be removed with an appropriate metal polish or non-abrasive cleaner.

Patients with goiter, thyroid nodules, or other thyroid diseases are at risk of developing thyroid hyperfunction (hyperthyroidism) from the usage of large amounts of iodine. In this patient population, povidone-iodine solution should not be applied for an extended period of time and to large areas of the skin unless strictly indicated. Even after the end of the treatment one should look for the early symptoms of possible hyperthyroidism and if necessary, the thyroid function should be monitored.

4.5 Interaction with other medicinal products 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 weakening of the effects of both substances. Products containing mercury, silver, hydrogen peroxide, and taurolidine may interact with povidone-iodine and should not be used concomitantly.

4.6 Pregnancy and lactation

During pregnancy and lactation, povidone-iodine should only be used if strictly indicated and its use should be kept to the absolute minimum. Because of the ability of iodine to pass through the placenta and be secreted in breast milk, and because of the increased sensitivity of the fetus and newborn to iodine, no large amounts of povidone-iodine should be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Rarely. Hypersensitive skin reactions may occur (e.g., delayed contact -allergic reactions, which can appear in the form of pruritus, erythema, small blisters or similar manifestations).

In single cases acute, generalized, allergic reactions, with drop in blood pressure and/or dyspnea (anaphylactic reactions) have been reported.

4.9 Overdose

Acute Iodine toxicity is manifested by abdominal symptoms, anuria, circulatory collapse, laryngeal edema resulting in asphyxia, or pulmonary edema and metabolic abnormalities.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Betadine Surgical scrub has a rapid and prolonged germicidal action against a wide spectrum of pathogenic organisms including both Gram-positive and Gram-negative bacteria, fungi, protozoa, and viruses. It is also active against bacterial spores. In the presence of blood, serum, purulent exudates and necrotic tissue, its activity persists as long as the colour remains. The golden brown colour serves to highlight the disinfected areas. A broad-spectrum antiseptic, bactericidal, virucidal sudsing skin cleanser for pre-and-postoperative scrubbing or washing by hospital operating room personnel; for

preoperative use on patients; and general use as an antiseptic microbicide in physician's office. Forms rich, golden lather.

Povidone-iodine surgical scrub is intended for topical application.

Povidone-iodine is an iodophore, which is used as a disinfectant and antiseptic mainly for the treatment of contaminated wounds and pre-operative preparation of the skin and mucous membranes.

Iodophores are loose complexes of iodine and carrier polymers. Solutions of Povidone-iodine gradually release Iodine to exert an effect against bacteria, fungi, viruses, protozoa, cysts, and spores; povidone-iodine is thus less potent than preparations containing free iodine, but it is less toxic.

Povidone-iodine retains the bactericidal activity of iodine but is less potent, therefore causes less irritation to skin and mucous membranes. In-vitro HIV appears to be completely inactivated by Povidone-iodine preparations.

5.2 Pharmacokinetic properties

The product is intended for topical application.

5.3 Preclinical safety data

None stated.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

1. Superamide
2. Sodium Hydroxide
3. Tabonic SE 305
4. Purified Water

6.2 Incompatibilities

None reported.

6.3 Shelf life

18 months.

6.4 Special precautions for storage

Store protected from light at a temperature not exceeding 30⁰C.

Replace the cap tightly after use.

6.5 Nature and contents of container

Betadine Surgical Scrub 7.5% w/v is supplied as Amber PET Bottle of 50 ml enclosed in carton with a pack insert and Brown HDPE bottle of 500 ml.

6.6 Special precautions for disposal and other handling

None stated.

7. MARKETING AUTHORISATION HOLDER

Modi-Mundipharma Private Ltd., 1400, Modi Tower, 98, Nehru Place, New Delhi 110019, India

8. MARKETING AUTHORISATION NUMBER(S)

Rwanda FDA-HMP-MA-0922

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

21/02/2024.

10. DATE OF REVISION OF THE TEXT

20/02/2029.