

For the use only of a Registered Medical Practitioner or
a Hospital or a Laboratory.

Povidone-Iodine Cleansing Solution USP 7.5%

Betadine™

Surgical Scrub

DESCRIPTION

Povidone-iodine is iodine complexed with povidone (polyvinyl-pyrrolidone). It is yellowish brown to reddish brown amorphous powder. Its chemical name is 2-Pyrrolidinone, 1-ethenyl-, homopolymer, compound with iodine.

Povidone iodine is soluble in water and ethanol (95%), and practically insoluble in chloroform, acetone and ether.

Betadine™ Surgical Scrub supplied as dark brown coloured viscous liquid.

Formula:

Povidone-iodine USP 7.5 % w/v
(available iodine 0.75% w/v)
Purified water q.s

INDICATIONS AND USAGE

Pre and post-operative scrubbing or washing by operating personnel. Pre and post-operative use on patients and general use in physician's office.

PHARMACOLOGY

Pharmacodynamics/Pharmacokinetics

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 post-operative scrubbing or washing by hospital operating room personnel; for pre-operative 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.

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Carton A/w of **Betadine Surgical Scrub - PI**
Actual Size : 70 x 210 mm Same Size Print Out
3.2.2016/NewSkyCreativeGroup (ND0216)

**DOSAGE AND ADMINISTRATION
FOR EXTERNAL USE ONLY**

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 (1ml. 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.

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.

WARNING AND PRECAUTIONS

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 discolour 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.

INTERACTIONS

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 tauridine may interact with Povidone-Iodine and should not be used concomitantly.

Note: Due to the oxidative effect of Povidone-Iodine

solution various diagnostic agents can show false-positive lab results (e.g. tests with toluidine or gum guaiac for the determination of hemoglobin or glucose in the stool or the urine).

Absorption of iodine from Povidone-Iodine may interfere with thyroid function tests. During the use of Povidone-Iodine solution the iodine uptake of the thyroid can be lowered; this can lead to interference with various investigations (thyroid scintigraphy, determination of PBI [protein-bound iodine], radioiodine diagnostics) and can make a planned treatment of the thyroid with iodine (radioiodine therapy) impossible after the end of the treatment, an appropriate interval should be allowed before a new scintigram is carried out.

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 foetus and newborn to iodine, no large amounts of Povidone-Iodine should be used during pregnancy and lactation.

ADVERSE REACTIONS

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.

OVERDOSAGE & TREATMENT

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.

PHARMACEUTICAL PARTICULARS

Incompatibilities: None Reported

Shelf Life: 18 months from the date of manufacturing.

Storage precautions: Store protected from light at a temperature not exceeding 30°C. Replace the cap tightly after use.

Keep all medicines out of reach of children.

Pack Size : Betadine™ Surgical Scrub is supplied in Amber coloured pet bottle of 50 ml fitted with HDPE caps and in 500 ml HDPE bottle.

Manufactured by :
G.S. Pharmbutor Pvt. Ltd.,
B-172, Industrial Area, Behror – 301 701,
Rajasthan, India.

TM : Trade Mark

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