PATIENT INFORMATION LEAFLET

BETADINE SURGICAL SCRUB 7.5% (Povidone-Iodine Cleansing Solution USP)

Povidone-Iodine 7.5% w/v (available Iodine 0.75% w/v)

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor.

In this leaflet:

1. WHAT BETADINE SURGICAL SCRUB 7.5% IS AND WHAT IT IS USED FOR

Betadine Surgical Scrub 7.5% is a topical surgical scrub 7.5% and is used for the pre- and post-operative scrubbing or washing by operating personnel. It is for Pre-operative and post-operative use on patients and general use in physician's office.

2. BEFORE YOU USE BETADINE SURGICAL SCRUB 7.5%

Do not use Betadine Surgical Scrub 7.5%

- if you are allergic (hypersensitive) to Iodine or Povidone or any of the other ingredients of Betadine Surgical Scrub 7.5%.

- 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.

Warnings and Precautions

Betadine Surgical Scrub 7.5% is 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, 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 taurolidine 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, unless strictly indicated.

3. HOW TO USE BETADINE SURGICAL SCRUB 7.5%

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 (1 ml. is sufficient to cover an area of 125-130 cm'), 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.

If you use more Betadine Surgical Scrub 7.5% than you should

Betadine surgical scrub is for topical use only. Excess solution applied can be easily washed off with water. In case of overdose or accidental oral ingestion, 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Betadine Surgical Scrub 7.5% can cause side effects, although not everybody gets them.

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.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or health care provider.

5. HOW TO STORE BETADINE SURGICAL SCRUB 7.5%

Keep out of the reach and sight of children.

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

Do not use Betadine Surgical Scrub 7.5% after the expiry date which is stated on the label/carton.

Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how to dispose off the medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What Betadine Surgical Scrub 7.5% contains

The active substance is Povidone-Iodine.

The other ingredients are Tabonic SE - 305, Superamide, Sodium Hydroxide BP and Purified water.

What Betadine Surgical Scrub 7.5% looks like and contents of the pack

Betadine Surgical Scrub 7.5% is dark brown coloured clear viscous liquid.

Betadine Surgical Scrub 7.5% is available in the following packs :

a) Amber coloured PET bottle of 50 ml enclosed in a carton with a pack insert.
b) HDPE bottle of 500 ml.

Registration number of Betadine Surgical Scrub is Rwanda FDA-HMP-MA-0922.

Market Authorization Holder

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