

PATIENT INFORMATION LEAFLET

BETADINE STANDARDISED MICROBICIDAL SOLUTION 10% (Povidone-Iodine Topical Solution USP)

Povidone-Iodine 10% w/v (available Iodine 1.0% 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.

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1. What Betadine Standardised Microbicidal Solution 10% is and what it is used for
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1. WHAT BETADINE STANDARDISED MICROBICIDAL SOLUTION 10% IS AND WHAT IT IS USED FOR

Betadine Standardised Microbicidal Solution 10% is a topical microbicidal solution and is used for the following :

- a) For the disinfection of wounds, lacerations, abrasion and burns.
- b) For the prophylaxis against infection in hospital and surgery procedure.
- c) For the preparation of skin and in mucous membranes prior to surgery.
- d) In Post-operative application to protect against infection.
- e) For the treatment of infected skin conditions.

2. BEFORE YOU USE BETADINE STANDARDISED MICROBICIDAL SOLUTION 10%

Do not use Betadine Standardised Microbicidal Solution 10%

- if you are allergic (hypersensitive) to Iodine or Povidone or any of the other ingredients of Betadine Standardised Microbicidal Solution 10%
- 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.
- If local irritation or sensitivity develops, discontinue the treatment.

Warnings

Prolonged exposure to wet solution may cause irritation or rarely, severe skin reactions. Chemical burns of skin due to "pooling" may occur. Do not heat prior to application. Keep out of the reach of children.

Patients with goiter, thyroid nodules, or other thyroid diseases are at risk of developing thyroid hyperfunction (hyperthyroidism) from the administration 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. New-borns and small infants are at increased risk of developing hypothyroidism from the administration of large amounts of iodine. A check of the child's thyroid function may be necessary. Any possible oral ingestion of Povidone-Iodine by the infant must be absolutely avoided.

Betadine Standardised Microbicidal Solution 10% is used for external use only.

Caution : If local irritation or sensitivity develops, discontinue the use and consult your doctor.

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 solution 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 new-born to Iodine, no large amounts of Povidone-Iodine should be administered during pregnancy and lactation. Povidone-Iodine use may induce transient hypothyroidism with elevation of TSH in the foetus or in the new-born. A check of the child's thyroid function may be

necessary. Any possible oral ingestion of the solution by the Infant must be absolutely avoided.

EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

It has no effect on the person's ability to drive and perform potentially hazardous tasks such as operating machinery.

3. HOW TO USE BETADINE STANDARDISED MICROBICIDAL SOLUTION 10%

- **FOR EXTERNAL USE ONLY**

Apply full strength as often as needed as a paint or wet soak. Allow to dry before applying surgical drapes and avoid 'pooling' beneath the patient. Prolonged exposure to the solution may cause irritation or rarely, severe skin reaction. In rare instance of local irritation or sensitivity, discontinue use.

If you use more Betadine Standardised Microbicidal Solution 10% than you should

In case of 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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Betadine Standardised Microbicidal Solution 10% 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. The long-term use of Povidone-Iodine solution for the treatment of wounds and burns over extensive areas of the skin can lead to a notable uptake of iodine. In isolated cases, patients with a history of thyroid disease can develop hyperfunction of the thyroid (Iodine induced hyperthyroidism), sometimes with symptoms such as tachycardia or restlessness. Following uptake of large amounts of Povidone-Iodine (e.g., in the treatment of burns), the appearance of additional disorders of electrolyte imbalance and abnormal blood osmolarity, impairment of renal function with acute renal failure and metabolic acidosis have been described in the use of iodine-containing products.

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

5. HOW TO STORE BETADINE STANDARDISED MICROBICIDAL SOLUTION 10%

Keep all medicines 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 Standardised Microbicidal Solution 10% after the expiry date which is stated on the label/carton or bottle.

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

6. FURTHER INFORMATION

What Betadine Standardised Microbicidal Solution 10% contains

The active substance is Povidone-Iodine USP 10% w/v (Available Iodine 1% w/v).

The other ingredients are Citric Acid Monohydrate BP, Dibasic Sodium Phosphate anhydrous USP, Glycerin BP, Alphox 200, Potassium Iodate BP, Sodium Hydroxide BP & Purified water BP.

What Betadine Standardised Microbicidal Solution 10% looks like and contents of the pack

Betadine Standardised Microbicidal Solution 10% is a clear dark brown liquid free from foreign matter.

Betadine Standardised Microbicidal Solution 10% is available in the following packs :

- a) Amber coloured PET bottle of 50 ml enclosed in a carton with pack insert.
- b) Amber coloured PET bottle of 100 ml enclosed in carton with pack insert.
- c) Brown HDPE bottle of 500 ml.

Registration number of Betadine Standardised Microbicidal Solution 10% is Rwanda FDA-HMP-MA-1381.

Market Authorization Holder

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For any information about this medicinal product, please contact the local representative of the supplier as mentioned below:

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