

## **PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER**

### **BETADINE ANTISEPTIC CREAM 5% (Povidone-Iodine Cream) Povidone-Iodine USP 5% w/w (Available Iodine 0.5% w/w)**

**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 ANTISEPTIC CREAM 5% IS AND WHAT IT IS USED FOR**

Betadine Antiseptic Cream 5% is a topical microbicidal cream and is used for the prevention of infection in burns, cuts, abrasions, poison ivy rash and insect bites. Betadine Antiseptic Cream 5% is also used in the treatment of skin infections, including infections of varicose & decubitus ulcers.

#### **2. BEFORE YOU USE BETADINE ANTISEPTIC CREAM 5%**

**Do not use Betadine Antiseptic Cream 5%**

- if you are allergic (hypersensitive) to Iodine or Povidone or any of the other ingredients of Betadine Antiseptic Cream 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 Antiseptic Cream 5% is intended for topical use only.

In instances of skin irritation or contact dermatitis or hypersensitivity, discontinue use. 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 application of large amounts of iodine. In this patient population, Povidone-Iodine cream 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. Newborns and small infants are at increased risk of developing hypothyroidism from the administration of large amounts of iodine. Because of the permeable nature of their skin and the increased sensitivity to iodine, the use of Povidone-Iodine should be kept to the absolute minimum in newborns and small infants. 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. Blue stains on starched linen will wash off with soap and water.

Not for use in infections in children below 2 years of age.

### **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 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 cream may interfere with thyroid function tests. During the use of Povidone-Iodine preparations 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 administered during pregnancy and lactation, unless strictly indicated. Povidone- Iodine use may induce transient hypothyroidism with elevation of TSH in the foetus or in the newborn. A check of the child's thyroid function may be necessary.

### **3. HOW TO USE BETADINE ANTISEPTIC CREAM 5%**

#### **• FOR EXTERNAL USE ONLY**

Clean and dry the affected area, then apply the cream as prescribed. A dressing may be applied if required.

#### **If you use more Betadine Antiseptic Cream 5% than you should**

In case of overdose, acute iodine toxicity is manifested by abdominal symptoms, anuria, circulatory collapse, laryngeal oedema resulting in asphyxia, or pulmonary edema and metabolic abnormalities.

Treatment is symptomatic and supportive.

### **4. POSSIBLE SIDE EFFECTS**

Like all medicines, Betadine Antiseptic Cream 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.

The long-term use of Povidone- Iodine preparations 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 usage 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 or health care provider.

## 5. HOW TO STORE BETADINE ANTISEPTIC CREAM 5%

Keep out of the reach and sight of children.

Store protected from light at a temperature not exceeding 30°C. Do not freeze.

Replace the cap tightly after use.

Do not use Betadine Antiseptic Cream 5% after the expiry date which is stated on the label/carton or bottle.

Medicines should not be disposed of 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 Antiseptic Cream 5% contains

The active substance is Povidone-Iodine.

The other ingredients are Cetostearyl Alcohol BP, Light Liquid Paraffin BP, Glycerin BP, Emulgade A6, Emulgin 825, Sodium Hydroxide BP and Purified Water BP.

### What Betadine Antiseptic Cream 5% looks like and contents of the pack

Betadine Antiseptic Cream 5% is a dark brown smooth cream having shining texture and is uniform in colour.

Betadine Antiseptic Cream 5% is available in the following packs :

- a) Tube of 10 g enclosed in a carton with pack insert.
- b) Tube of 20 g enclosed in a carton with pack insert.

Registration number of Betadine Antiseptic Cream 5% is Rwanda FDA-HMP-MA-1420.

### Supplier

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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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