

## **Package leaflet: Information for the user**

### **Betadine Surgical Scrub 75 mg/ml Cutaneous Solution Povidone Iodine**

**Read all of this leaflet carefully before you start using Betadine Surgical Scrub 75 mg/ml Cutaneous Solution.**

- Keep this leaflet. You may need to read it again.
- If you have any questions, ask your doctor or pharmacist.
- This medicine has been prescribed to 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 become serious, or if you notice any side effects not listed in this leaflet, stop using Betadine Surgical Scrub straightaway and tell your doctor or pharmacist.

#### **In this leaflet:**

1. What Betadine Surgical Scrub is and what it is used for
2. Before you use Betadine Surgical Scrub
3. How to use Betadine Surgical Scrub
4. Possible side effects
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#### **1. What Betadine Surgical Scrub 75 mg/ml Cutaneous Solution is and what it is used for**

Betadine Surgical Scrub contains povidone iodine which kills a wide range of germs including bacteria, viruses, fungi and simple organisms. Betadine Surgical Scrub is used as an antiseptic for pre-operative and post-operative treatment of skin. It is also used as a pre-operative surgical preparation.

#### **2. Before you use Betadine Surgical Scrub 75 mg/ml Cutaneous Solution**

##### **Do not use Betadine Surgical Scrub 75 mg/ml Cutaneous Solution:**

- if you are allergic (hypersensitive) to povidone iodine or any of the other ingredients listed.
- if you currently have or have ever had a thyroid problem, including swelling (nodular colloid goitre, endemic goitre or Hashimoto's thyroiditis), as using Betadine Surgical Scrub in these circumstances can further affect the function of your thyroid
- if you are currently having lithium therapy for depression as this type of medicine can interact with Betadine Surgical Scrub to affect the function of your thyroid
- on children under two years of age.

##### **Talk to your doctor or pharmacist before using Betadine Surgical Scrub 75 mg/ml Cutaneous Solution:**

- if your skin is broken (for example, due to a burn) as using Betadine Surgical Scrub in these circumstances may cause toxic levels of iodine to be absorbed into your blood
- If you currently have or have ever had a kidney problem as using Betadine Surgical Scrub in these circumstances may cause toxic levels of iodine to be absorbed into your blood

##### **Using other medicines**

Lithium (for depression) can interact with Betadine Surgical Scrub to affect the function of the thyroid gland. Therefore simultaneous use should be avoided.

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, before you use Betadine Surgical Scrub.

### **Pregnancy and breastfeeding**

If you know or think you might be pregnant, or are breastfeeding, talk to your doctor or pharmacist before using Betadine Surgical Scrub or any other medicine.

### **Other special precautions**

- Tell your doctor if you are due to have a thyroid test, faeces (stool) test or urine test, as Betadine Surgical Scrub may affect the results.
- Betadine Surgical Scrub can permanently discolour white gold jewellery and it is recommended that this type of jewellery should be removed before using the product.

### **3. How to use Betadine Surgical Scrub 75 mg/ml Cutaneous Solution**

For topical use on the skin only. Do NOT use Betadine Surgical Scrub inside your body.

#### **Adults, the elderly and children over 2 years of age:**

*For pre-operative skin disinfection by Operating Department personnel:* Wet hands with water. Pour about 5ml on the palm of the hand and spread over both hands. Without adding more water, rub the Scrub thoroughly for a minimum of 2 minutes. Clean thoroughly under the fingernails. Add a little water to develop a lather, and rinse thoroughly under running water.

*For pre-operative disinfection of patients' skin:* After the operative site is shaved, wet it with water. Apply Betadine Surgical Scrub and rub thoroughly for 2 minutes with a sterile gauze wetted with water. Develop a lather and rinse off.

#### **Must NOT be used on children under 2 years of age**

IF YOU ACCIDENTALLY SWALLOW ANY BETADINE SURGICAL SCRUB SEEK MEDICAL ADVICE IMMEDIATELY TAKING THE BOTTLE WITH YOU.

If you have further questions on the use of Betadine Surgical Scrub ask your doctor or pharmacist before use.

### **4. Possible unwanted effects**

Like all medicines, Betadine Surgical Scrub can cause unwanted effects, although these are uncommon.

Allergic-type reactions, including a rash or difficulty in breathing, have been reported uncommonly with products containing iodinated povidone (the active ingredient in Betadine Surgical Scrub). Although rare, Betadine 10% Surgical Scrub could also cause itching and burns on your skin.

Applying very large amounts of medicines containing iodinated povidone, or using such products over a long period of time, can occasionally cause thyroid disorders (symptoms of which include weight loss, increased appetite and sweating; or lack of energy and weight gain). Other effects that have been reported are increased amounts of acid in your blood (the main symptoms are shortness of breath, confusion and lethargy), and kidney failure (symptoms include difficulty in urinating, thirst and a dry mouth, and pain in one side of your back).

Should you suffer from any of these unwanted effects, or if you notice any unwanted effects not listed in this leaflet, stop using Betadine Surgical Scrub straightaway and tell your doctor or pharmacist.

### **5. How to store Betadine Surgical Scrub 75 mg/ml Cutaneous Solution**

Keep out of the reach and sight of children.

Do not use Betadine Surgical Scrub after the expiry date stated on the label. The expiry date refers to the last day of that month.

Store below 25°C. Store in the original package to protect from light.

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

## **6. Further information**

### **What Betadine Surgical Scrub 75 mg/ml Cutaneous Solution contains**

The active substance is povidone iodine. Each ml of Betadine Surgical Scrub contains 75 mg povidone iodine (equivalent to 8 mg/ml available iodine).

The other ingredients are: Sulphated nonylphenoxypoly (oxyethylene) ethanol ammonium salt, Lauric diethanolamide, Ethoxylated lanolin 50%, Hydroxyethylcellulose, Sodium hydroxide (E524) and Purified Water.

### **What Betadine Surgical Scrub 75 mg/ml Cutaneous Solution looks like and contents of the pack**

Betadine Surgical Scrub is a dark-brown coloured solution and is sold in plastic (HDPE) bottles containing either 500 ml or 5 l of product. Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Mundipharma Pharmaceuticals Ltd., Millbank House, Arkle Road, Sandyford, Dublin 18, Ireland

### **Manufacturer**

SSL International plc, Whitehouse Industrial Park, Traynor Way, Peterlee, Durham. SR8 2RU, United Kingdom.

This leaflet was last approved in July 2019.