

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

### **Betadine Alcoholic 100 mg/ml Cutaneous Solution** Povidone Iodine

**Read all of this leaflet carefully before you start using Betadine Alcoholic 100 mg/ml Cutaneous Solution.**

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor 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 become serious, or if you notice any side effect not listed in this leaflet, stop using Betadine Alcoholic Solution straightaway and tell your doctor or pharmacist.

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

1. What Betadine Alcoholic Solution is and what it is used for
2. Before you use Betadine Alcoholic Solution
3. How to use Betadine Alcoholic Solution
4. Possible side effects
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#### **1. What Betadine Alcoholic 100 mg/ml Cutaneous Solution is and what it is used for**

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

#### **2. Before you use Betadine Alcoholic 100 mg/ml Cutaneous Solution**

##### **Do not use Betadine Alcoholic 100 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 Alcoholic Solution 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 Alcoholic Solution to affect the function of your thyroid
- on children under two years of age.

##### **Talk to your doctor or pharmacist before using Betadine Alcoholic 100 mg/ml Cutaneous Solution**

- if your skin is broken (for example, due to a burn) as using Betadine Alcoholic Solution 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 Alcoholic Solution 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 Alcoholic Solution 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 Alcoholic Solution.

### **Pregnancy and breastfeeding**

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

### **Other Special Precautions**

- Flammable – this preparation contains alcohol. Do not allow pooling of Betadine Alcoholic Solution to occur, and ensure the skin and surrounding drapes are dry when use is to be followed by diathermy.
- Tell your doctor if you are due to have a thyroid test, faeces (stool) or urine test, as Betadine Alcoholic Solution may affect the results.
- Betadine Alcoholic Solution can permanently discolour white gold jewellery and it is recommended that this type of jewellery should be removed before using Betadine Alcoholic Solution.

### **3. How to use Betadine Alcoholic 100 mg/ml Cutaneous Solution**

For topical use on the skin only: Do NOT use Betadine Alcoholic Solution inside your body.

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

Apply directly to the affected area of skin as required.

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

IF YOU ACCIDENTALLY SWALLOW ANY BETADINE ALCOHOLIC SOLUTION SEEK MEDICAL ADVICE IMMEDIATELY, TAKING THE BOTTLE WITH YOU.

If you have any further questions on the use of Betadine Alcoholic Solution ask your doctor or pharmacist before use.

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

Like all medicines, Betadine Alcoholic Solution 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 povidone iodine (the active ingredient in Betadine Alcoholic Solution). Although rare, Betadine Alcoholic Solution could also cause itching and burns on your skin.

Applying very large amounts of medicines containing povidone iodine, 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 lacking 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 Alcoholic Solution straightaway and tell your doctor or pharmacist.

### **5. How to store Betadine Alcoholic 100 mg/ml Cutaneous Solution**

Flammable: Store away from sources of ignition.

Keep out of the reach and sight of children.

Do not use Betadine Alcoholic Solution 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 Alcoholic 100 mg/ml Cutaneous Solution contains**

The active substance is povidone iodine. Each ml of Betadine Alcoholic Solution contains 100mg povidone iodine (equivalent to 10 mg/ml available iodine).

The other ingredients are glycerol (E422), industrial methylated spirit, nonoxynol 9, citric acid monohydrate (E330), dibasic sodium phosphate (anhydrous) (E339), sodium hydroxide (E524) and purified water.

### **What Betadine Alcoholic 100 mg/ml Cutaneous Solution looks like and contents of the pack**

Betadine Alcoholic Solution is a dark brown coloured solution with an odour of alcohol and is sold in plastic (HDPE) bottles containing 500 ml of product.

### **Marketing Authorisation Holder and Manufacturer**

The name and address of the marketing authorisation holder is Mundipharma Pharmaceuticals Ltd., Millbank House, Arkle Road, Sandyford, Dublin 18, Ireland.

The name and address of the manufacturer is SSL International plc, Whitehouse Industrial Park, Traynor Way, Peterlee, Durham. SR8 2RU, UK.

This leaflet was last approved in July 2019.