

## **Package Leaflet: Information for the User**

### **Betadine 10% w/w Ointment** Iodinated Povidone

**Read all of this leaflet carefully because it contains important information for you.**

This medicine is available without prescription. However, you still need to use Betadine 10% w/w Ointment carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice
- You must contact a doctor if your symptoms worsen or do not improve
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, stop using Betadine 10% w/w Ointment straightaway and tell your doctor or pharmacist.

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

1. What Betadine 10% w/w Ointment is and what it is used for
2. Before you use Betadine 10% w/w Ointment
3. How to use Betadine 10% w/w Ointment
4. Possible side effects
5. How to store Betadine 10% w/w Ointment
6. Further information

#### **1. What Betadine 10% w/w Ointment is and what it is used for**

Betadine 10% w/w Ointment contains Iodinated Povidone which kills a wide range of germs including bacteria, viruses, fungi and simple organisms.

Betadine 10% w/w Ointment is used as an antiseptic for the management of minor damage or infection of the skin.

#### **2. Before you use Betadine 10% w/w Ointment**

##### **Do not use Betadine 10% w/w Ointment:**

- if you are allergic (hypersensitive) to Iodine, polyvinylpyrrolidone 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 10% w/w Ointment 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 10% w/w Ointment to affect the function of your thyroid
- on children under two years of age.

##### **Talk to your doctor or pharmacist before using Betadine 10% w/w Ointment:**

- If your skin is broken (for example, due to a burn) as using Betadine 10% w/w Ointment 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 10% w/w Ointment in these circumstances may cause toxic levels of iodine to be absorbed into your blood
- when you know you are due to have a thyroid, faeces (stool) or urine test as Betadine 10% w/w Ointment may affect the results.

If the above applies to you or you are not sure whether it does, speak to your doctor or pharmacist before using Betadine Ointment.

#### **Using other medicines**

Lithium therapy (for depression) can interact with Betadine 10% w/w Ointment to affect the function of the thyroid gland. Therefore, concurrent 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 10% w/w Ointment.

### **Pregnancy and breastfeeding**

If you know or think you might be pregnant, or are breastfeeding, talk to your doctor or pharmacist before using Betadine 10% w/w Ointment or any other medicine.

### **3. How to use Betadine 10% w/w Ointment**

For topical use on the skin only: Do NOT use Betadine 10% w/w Ointment inside your body.

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

Apply once or twice daily for a maximum of 14 days.

The affected skin should be cleaned and dried. Betadine 10% w/w Ointment should then be applied to the affected area. A dressing or bandage may then be used to cover the affected area.

If symptoms do not get better, consult your doctor or pharmacist.

#### **Betadine 10% w/w Ointment must NOT be used on children under 2 years of age.**

IF YOU ACCIDENTALLY SWALLOW ANY BETADINE 10% W/W OINTMENT SEEK MEDICAL ADVICE IMMEDIATELY TAKING THE TUBE, CARTON AND THIS LEAFLET WITH YOU.

Betadine 10% w/w Ointment can permanently discolour white gold jewellery and it is recommended that this type of jewellery should be removed before using Betadine 10% w/w Ointment.

If you have any further questions on the use of Betadine 10% w/w Ointment ask your doctor or pharmacist before use.

### **4. Possible Unwanted Effects**

Like all medicines, Betadine 10% w/w Ointment may cause side 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 10% w/w Ointment). Although rare, Betadine 10% w/w Ointment 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 10% w/w Ointment straightaway and tell your doctor or pharmacist.

### **5. How to store Betadine 10% w/w Ointment**

Keep out of the reach and sight of children.

Do not use Betadine 10% w/w Ointment after the expiry date stated on the end (crimp) of the tube and on the end of the carton.

Do not store above 25°C.

Do not use if you notice any damage to the container.

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

## **6. Further information**

### **What Betadine 10% w/w Ointment contains**

The active substance is iodinated povidone 10%w/w. (Equivalent to 1% w/w available iodine).

The other ingredients are: Macrogol 4000; Macrogol 1000; Macrogol 1500; Macrogol 400; sodium hydrogen carbonate (E500) and purified water.

### **What Betadine 10% w/w Ointment looks like, and contents of the pack**

Betadine 10% w/w Ointment is an ointment and is sold in an aluminium tube (with a plastic polyethylene cap), with an outer cardboard carton, containing 80 g of product.

### **Marketing Authorisation Holder**

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

### **Manufacturer**

The name and address of the manufacturer is Seton Healthcare Group, Tubiton House, Medlock Street, Oldham, OL1 3HS, UK.

This leaflet was last revised in July 2019.