

Betadine
Dry Powder 25mg/g Cutaneous Spray
Povidone iodine.

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Keep this leaflet. You may need to read it again. Ask your pharmacist if you need more information or advice. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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1. What Betadine Dry Powder Spray is and what it is used for

Betadine Dry Powder Spray contains povidone iodine, which kills a wide range of germs, including bacteria, viruses, fungi and simple organisms. Betadine Dry Powder Spray is used as an antiseptic for the treatment and prevention of infection in minor skin trauma including burns, cuts and other minor injuries.

2. What you need to know before you use Betadine Dry Powder Spray

Do not use Betadine Dry Powder Spray:

- If you are allergic to povidone iodine or any of the other ingredients of this medicine (listed in section 6).
- 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 Dry Powder Spray in these circumstances can further affect the function of your thyroid.
- If you are on concurrent lithium therapy
- On children under two years of age.
- Betadine Dry Powder Spray should not be used in serous (fluid filled) cavities.

If you are not sure whether any of the above apply to you, speak to your doctor or pharmacist before using Betadine Dry Powder Spray.

Warnings and precautions

Talk to your doctor or pharmacist before using Betadine Dry Powder Spray

- If your skin is broken (for example, due to a burn) as using Betadine Dry Powder Spray 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 Dry Powder Spray in these circumstances may cause toxic levels of iodine to be absorbed into your blood.
- Avoid inhalation.
- Avoid contact with the eyes.

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

Other medicines and Betadine Dry Powder Spray

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. In particular, you should tell your doctor if you are taking the following:

- Lithium (for depression, mania and bipolar disorder) can interact with Betadine Dry Powder Spray to affect the function of the thyroid gland. Therefore, concurrent use should be avoided.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Other Special Precautions

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

3. How to use Betadine Dry Powder Spray

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

For topical use on the skin only.

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

Shake the can well before use. Spray the affected area from a distance of 6-10 inches (15-25cm) until a dusting of powder is deposited. If necessary, the treated area may be covered with a dressing.

Only use Betadine Dry Powder Spray in adults and children aged 2 years and older.

If you accidentally swallow any Betadine Dry Powder Spray: You should go to your nearest Accident and Emergency department or contact your doctor immediately. Take this leaflet and any other packaging with you so they know what you have taken. If you have any further questions on the use of Betadine Dry Powder Spray, ask a doctor or pharmacist before use.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If you experience any of the following side effects stop using Betadine Dry Powder Spray and go to your nearest Accident and Emergency department or contact your doctor immediately:

- Allergic-type reactions, including difficulty breathing or swallowing, a rash, swelling of the face, lips, throat or tongue.

You may also experience the following side effects:

- Betadine Dry Powder Spray could also cause itching and burns on your skin (rarely).
- local irritation
- 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 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).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance, Earlsfort Terrace IRL - Dublin 2. Tel: +353 1 6764971, Fax: +353 1 6762517, Website: [http:// www.hpra.ie](http://www.hpra.ie), e-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Betadine Dry Powder Spray

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is printed on the bottom of the aerosol can. The expiry date refers to the last day of that month. Do not store above 25°C. Store away from direct heat and sunlight. Do not puncture, break or burn the can even if apparently empty. Do not expose to temperatures exceeding 50°C. Do not throw away any medicines via wastewater or household waste.

Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

6. Contents of the pack and other information

What Betadine Dry Powder Spray contains:

- The active substance is povidone iodine and each gram of powder contains 25mg of povidone iodine
- The other ingredients are: Isopropyl myristate, N-pentane, Butane 40 (E943) and Soya lecithin.

What Betadine Dry Powder Spray looks like and contents of the pack

Betadine Dry Powder Spray is a topical spray and is sold in an aerosol can containing 100ml of product.

Marketing Authorisation Holder

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

Manufacturer

Pharmasol Ltd, North Way, Walworth Industrial Estate, Andover, SP10 5AZ, UK.

For information in large print, audio CD or braille please contact the Marketing Authorisation Holder.

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