

B. PACKAGE LEAFLET

Betadine Dry Powder 25mg/g Topical Spray

Povidone Iodine

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 Dry Powder Spray carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask a doctor or 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 Dry Powder Spray immediately and tell a doctor or pharmacist.

In this leaflet:

1. What Betadine Dry Powder Spray is and what it is used for
2. Before you use Betadine Dry Powder Spray
3. How to use Betadine Dry Powder Spray
4. Possible side effects
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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 wounds including ulcers, small areas of burns, cuts and other minor injuries.

2. Before you use Betadine Dry Powder Spray

Do not use Betadine Dry Powder Spray:

- If you are allergic (hypersensitive) to povidone iodine or any of the other ingredients listed in section 6 of this leaflet.
- If you currently have or have ever had a thyroid problem, including swelling (nodular colloid goitre, endemic goitre or Hashimoto's thyroklisis), as using Betadine Dry Powder Spray in these circumstances can further affect the function of your thyroid
- On children under two years of age.
- Betadine Dry Powder Spray should not be used in serous 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.

Take special care with 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.

Using other medicines

Please tell a doctor or pharmacist if you are taking, or have recently taken, any other medicines, including medicines obtained without a prescription, before you use Betadine Dry Powder Spray. In particular, you should tell the doctor if you are taking the following:

- Lithium (for depression), which 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 know you are, or think you might be pregnant, or are breastfeeding, talk to a doctor or pharmacist before using Betadine Dry Powder Spray, or any other 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 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

For topical use on the skin only.

Adults and children aged 2 years and older:

Shake the can well before use. Spray the affected area from a distance of 6-10 inches (15-25 cm) 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, Betadine Dry Powder Spray may 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).
- 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).

Should you suffer from any of these side effects, or if you notice any side effects not listed in this leaflet, stop using Betadine Dry Powder Spray immediately and tell a doctor or pharmacist.

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 the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard
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 out of the sight and reach of children.

Do not use Betadine Dry Powder Spray 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.

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 Dry Powder Spray contains

- The active substance is povidone iodine 2.5%w/w. Each gram of Betadine Dry Powder Spray contains 25 mg 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 100 ml of product.

Marketing Authorisation Holder

Napp Pharmaceuticals Ltd, Cambridge Science Park, Milton Road, Cambridge, CB4 0GW, UK.

Manufacturer

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

Pharmaserve North West Ltd., 9 Arkwright Road, Astmoor Industrial Estate, Runcorn, Cheshire, WA7 1NU, UK.

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

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