

Package leaflet: Information for the user

Betadine 100 mg/ml Antiseptic Paint 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 Antiseptic Paint 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 your 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 Antiseptic Paint straightaway and tell your doctor or pharmacist.

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1. What Betadine 100 mg/ml Antiseptic Paint is and what it is used for

Betadine Antiseptic Paint contains povidone iodine which kills a wide range of germs including bacteria, viruses, fungi and simple organisms. Betadine Antiseptic Paint is used for the prevention and treatment of skin infections such as cold sores, and in grazes, abrasions, cuts and wounds.

2. Before you use Betadine 100 mg/ml Antiseptic Paint

Do not use Betadine 100 mg/ml Antiseptic Paint:

- 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 Antiseptic Paint 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 Antiseptic Paint to affect the function of your thyroid
- on children under two years of age.

Talk to your doctor or pharmacist before using Betadine 100 mg/ml Antiseptic Paint

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

Pregnancy and breastfeeding

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

Other Special Precautions

- Flammable – this preparation contains alcohol. Allow to dry after use, and avoid exposure to sources of ignition.
- Tell your doctor if you are due to have a thyroid test, faeces (stool) or urine test, as Betadine Antiseptic Paint may affect the results.
- Betadine Antiseptic Paint can permanently discolour white gold jewellery and it is recommended that this type of jewellery should be removed before using Betadine Antiseptic Paint.

3. How to use Betadine 100 mg/ml Antiseptic Paint

For topical use on the skin only: Do NOT use Betadine Antiseptic Paint inside your body.

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

Apply directly to the affected area of skin once or twice daily as directed. Allow to dry, and cover with a dressing if desired.

Must NOT be used on children under 2 years of age

IF YOU ACCIDENTALLY SWALLOW ANY BETADINE ANTISEPTIC PAINT SEEK MEDICAL ADVICE IMMEDIATELY, TAKING THE BOTTLE, CARTON AND THIS LEAFLET WITH YOU.

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

4. Possible unwanted effects

Like all medicines, Betadine Antiseptic Paint 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 Antiseptic Paint). Although rare, Betadine Antiseptic Paint 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 Antiseptic Paint straightaway and tell your doctor or pharmacist.

5. How to store Betadine 100 mg/ml Antiseptic Paint

Flammable: Store away from sources of ignition.

Keep out of the reach and sight of children.

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

Store below 25°C.

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 100 mg/ml Antiseptic Paint contains

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

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

What Betadine 100 mg/ml Antiseptic Paint looks like and contents of the pack

Betadine Antiseptic Paint is a dark brown coloured solution with an odour of alcohol and is sold in clear glass bottles (with integral brush) containing 8 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.