

Betadine Antiseptic Topical Ointment®

Active ingredient: *povidone iodine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Betadine Antiseptic Topical Ointment. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Betadine Antiseptic Topical Ointment.**

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1. Why am I using Betadine Antiseptic Topical Ointment?

Betadine Antiseptic Topical Ointment contains the active ingredient povidone.

Betadine Antiseptic Topical Ointment is used as an antiseptic for the treatment of common skin infections such as infections of the skin around the nails, prevention of infections in minor burns, cuts and abrasions.

2. What should I know before I use Betadine Antiseptic Topical Ointment?

Warnings

BETADINE ANTISEPTIC TOPICAL OINTMENT IS FOR EXTERNAL USE ONLY.

Do not use Betadine Antiseptic Topical Ointment:

- if you are allergic to povidone or any of the ingredients listed at the end of this leaflet.
Always check the ingredients to make sure you can use this medicine.
- on extensive burn areas
- if you have a known hypersensitivity to povidone iodine, iodine polyvinylpyrrolidone or any excipients listed in the product description.
- if irritation, redness or swelling develops, discontinue treatment and consult a doctor.
- if you currently have or have ever had, a thyroid problem, including swelling (nodular colloid goitre, endemic goitre or Hashimoto's thyroiditis), as there may be a risk of developing hyperthyroidism from the administration of large amounts of iodine.
- for 4 weeks prior to treatment for cancer of the thyroid.
- during lithium therapy or mercury derivatives therapy

- over a long period and to large areas of the skin (e.g., not to more than 10% of the total body surface and for not longer than 14 days) unless strictly indicated.

Do not use in children below 2 years of age.

DO NOT USE IF TUBE SEAL IS BROKEN OR AFTER EXPIRY DATE.

Povidone-iodine preparations are expected to react with unsaturated organic compounds (e.g. blood, pus) and can lead to ineffectiveness of the preparation.

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other conditions
- have ever had a kidney problem as using this product may cause toxic levels of iodine to be absorbed into your blood, avoid inhalation and avoid contact with eyes

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Betadine Antiseptic Topical Ointment is not recommended during pregnancy. Check with your doctor if you are pregnant or intend to become pregnant.

Betadine Antiseptic Topical Ointment is not recommended during breastfeeding. Talk to your doctor if you are breastfeeding or intend to breastfeed.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Betadine Antiseptic Topical Ointment and affect how it works.

- Lithium (for depression) can interact with Betadine Antiseptic Topical Ointment to affect the function of the thyroid gland. Therefore, concurrent use should be avoided.
- Do not use other wound-treatment preparations containing enzymatic components at the same time as a povidone-iodine preparation as this can lead to ineffectiveness of both the preparations. The same thing can happen if disinfectants containing silver, hydrogen peroxide or taurolidine are used at the same time.
- Do not use at the same time or immediately after application of octenidine containing antiseptics in the same or adjacent sites, as this may lead to transient dark discolorations in the areas involved.
- The use of mercury containing wound-treatment products at the same time with povidone-iodine preparations can lead to the formation of a substance which can damage the skin.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Betadine Antiseptic Topical Ointment.

4. How do I use Betadine Antiseptic Topical Ointment?

When to use Betadine Antiseptic Topical Ointment

- Before applying the Povidone-iodine preparations ensure the area is clean. Povidone-iodine preparations may react with blood or pus and lead to ineffectiveness of the preparation.
- Apply directly to the affected area two to three times daily. The affected area may be bandaged.

How to use Betadine Antiseptic Topical Ointment

- Betadine Antiseptic Topical Ointment is for external use only.
- Do not heat prior to application.

If you use too much Betadine Antiseptic Topical Ointment

If you think that you have used too much Betadine Antiseptic Topical Ointment, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre in Australia (by calling **13 11 26**), or New Zealand **0800 POISON** or **0800 764 766**
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Betadine Antiseptic Topical Ointment?

Things you should do

- Tell your doctor if you are due to have a thyroid test, faeces (stool) or urine test, as Betadine Antiseptic Liquid Spray may affect the results
- Remind any doctor, dentist or pharmacist you visit that you are using Betadine Antiseptic Topical Ointment.
- **Avoid inhalation**
- **Avoid contact with the eyes.**
- Due to the oxidative effect of povidone-iodine preparations may show inaccurate results with diagnostic tests for the determination of blood or glucose in the stool or the urine.
- During the use of povidone-iodine preparations the iodine uptake of the thyroid can be lowered; this can lead to interference with various diagnostic investigations on the thyroid and can make a planned treatment of the thyroid with iodine impossible.

Driving or using machines

Betadine has no influence on the ability to drive and use machines.

Looking after your medicine

- Keep your medicine in a place where the temperature stays below 25°C.

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on window sills.

Keep it where young children cannot reach it.

Medicines should not be disposed of via wastewater or household waste.

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
Skin related • Red or inflamed skin • Peeling skin • Dry skin • Skin discolouration	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
Allergy related • difficulty breathing or swallowing, • rash, swelling of the face, lips, throat or tongue • itching, redness or small blisters (rarely). Skin related: • prolonged exposure to wet solution may cause redness and inflammation of the skin or severe skin reactions (rarely) or skin burns. Kidney related: • kidney failure (symptoms include difficulty in urinating, thirst and a dry mouth, and pain in one side of your back) has been reported.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

Serious side effects	What to do
Blood related: - increased amounts of acid in your blood (the main symptoms are shortness of breath, confusion and lethargy) have been reported. - electrolyte imbalance - abnormal blood osmolality Thyroid related: - thyroid disorders (symptoms of which include weight loss, increased appetite and sweating, or lack of energy and weight gain, racing pulse or a feeling of unrest) can occasionally occur from using very large amounts of such products over a long period of time.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

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

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to:

Australia, the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems.

New Zealand online at <https://nzphvc.otago.ac.nz/reporting>

By reporting side effects, you can help provide more information on the safety of this medicine.

7. Product details

This medicine is available over-the-counter without a doctor's prescription.

What Betadine Antiseptic Topical Ointment contains

Active ingredient (main ingredient)	Povidone
Other ingredients (inactive ingredients)	Macrogol 1000 Macrogol 1500 Macrogol 3350 Macrogol 400 Purified water Sodium bicarbonate
Potential allergens	N/A

Do not take this medicine if you are allergic to any of these ingredients.

What Betadine Antiseptic Topical Ointment looks like

Betadine Antiseptic Topical Ointment is a brown viscous ointment in a 25 g or 65 g tube

(AUST R 29561)

Who distributes Betadine Antiseptic Topical Ointment

Betadine Antiseptic Topical Ointment is supplied in Australia:

Sanofi Consumer Healthcare

87 Yarraman Place, Virginia,

Qld 4014 Australia.

Toll-free: 1800 818 806

Betadine Antiseptic Topical Ointment is supplied in New Zealand by:

sanofi-aventis new zealand limited

New Zealand

Toll free (NZ): 0800 283 684

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