

BETADINE ANTISEPTIC TOPICAL OINTMENT®

povidone-iodine (*poh-vi-dohn-ahy-uh-dahyn*)

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Betadine Antiseptic Topical Ointment. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

This medicine is available without prescription. However, you still need to use Betadine Antiseptic Topical Ointment carefully to get the best results from it.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may need to read it again.

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 effect not listed in this leaflet, stop using Betadine Antiseptic Topical Ointment immediately and tell a doctor or pharmacist.

WHAT BETADINE ANTISEPTIC TOPICAL OINTMENT IS USED FOR

Betadine Antiseptic Topical Ointment contains povidone iodine, which is used for the treatment of common skin infections.

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.

Always read the label. Avoid excessive heat.

Follow the directions for use. If symptoms persist, talk to your health professional.

BEFORE YOU USE BETADINE ANTISEPTIC TOPICAL OINTMENT

BETADINE ANTISEPTIC TOPICAL OINTMENT IS FOR EXTERNAL USE ONLY.

When you must not use it

- avoid application to extensive burn areas.
- known hypersensitivity to iodine or povidone. 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.
- it should not be used for 4 weeks prior to treatment for cancer of the thyroid.
- povidone iodine preparations should not be applied 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.
- on infants under 6 months of age.
- **DO NOT USE IF TUBE SEAL IS BROKEN OR AFTER EXPIRY DATE.**

Keep out of reach of children.

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 Antiseptic Topical Ointment, or any other medicine.

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

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

- Avoid inhalation.
- Avoid contact with the eyes.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. In particular, you should tell your doctor if you are taking the following:

- 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 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 taurididine 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

HOW TO USE BETADINE ANTISEPTIC TOPICAL OINTMENT]

Betadine Antiseptic Topical Ointment is for external use only.

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.

Do not heat prior to application.

If you do not understand the instructions, ask your doctor or pharmacist for help.

If you take too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre (telephone Australia 13 11 26 or New Zealand 0800 POISON or 0800 764766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much Betadine Antiseptic Topical Ointment. Do this even

if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE USING BETADINE ANTISEPTIC TOPICAL OINTMENT

Things you must do

Tell your doctor if you are due to have a thyroid test, faeces (stool) or urine test, as Betadine Antiseptic Topical Ointment may affect the results.

SIDE EFFECTS

Like all medicines, Betadine Antiseptic Topical Ointment may cause side effects, although not everybody gets them.

If you experience any of the following side effects stop using Betadine Antiseptic Topical Ointment 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
- itching, redness or small blisters (rarely).

You may also experience the following side effects:

- 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.
- increased amounts of acid in your blood (the main symptoms are shortness of breath, confusion and lethargy) have been reported.
- kidney failure (symptoms include difficulty in urinating, thirst and a dry mouth, and pain in one side of your back) has been reported.
- prolonged exposure to wet solution may cause redness and inflammation of the skin or severe skin reactions (rarely) or skin burns.

If your skin becomes irritated or sensitive, discontinue use.

Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

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.

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions.

Australia: www.tga.gov.au/reporting-problems

AFTER TAKING BETADINE ANTISEPTIC TOPICAL OINTMENT

Storage

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

Do not store Betadine Antiseptic Topical Ointment or any other medicine in the bathroom or near a sink. Do not leave it on a window sill or in the car.

Heat and dampness can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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

Ask your pharmacist how to dispose of medicines no longer required.

PRODUCT DESCRIPTION

What it looks like

A brown viscous ointment in a 25g or 65 g tube.

Ingredients

Active ingredients:

- Povidone iodine

Inactive ingredients:

- Macrogol 1000
- Macrogol 1500
- Macrogol 3350
- Macrogol 400
- Purified water
- Sodium bicarbonate

Supplier

Betadine Antiseptic Topical Ointment is supplied in Australia by:

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
Level 8, 56 Cawley Street, Ellerslie,
Auckland 1051, New Zealand

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