

BETADINE ANTISEPTIC LIQUID SPRAY®

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 Liquid Spray.

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 Liquid Spray 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 with the medicine. 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 Liquid Spray immediately and tell a doctor or pharmacist.

WHAT BETADINE ANTISEPTIC LIQUID SPRAY IS USED FOR

Betadine Antiseptic Liquid Spray contains povidone iodine and rapidly kills bacteria commonly responsible for wound and skin infections. For Antisepsis of minor cuts, abrasions, minor burns and the treatment of minor skin infections.

Always read the label. Contents under pressure.

Do not incinerate.

Follow the directions for use.

If symptoms persist, talk to your health professional.

BEFORE YOU USE BETADINE ANTISEPTIC LIQUID SPRAY

BETADINE ANTISEPTIC LIQUID SPRAY IS FOR EXTERNAL USE ONLY

When you must not take it

- known hypersensitivity to iodine or povidone or any of the ingredients listed in product description section. 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 using Betadine Antiseptic Liquid Spray in these circumstances can further affect the function of your thyroid.
- not recommended during pregnancy or breastfeeding.
- on children under 6 months of age.
- DO NOT USE IF CAP SEAL IS BROKEN OR AFTER EXPIRY DATE.

Medical advice should be sought for the treatment of more serious burns.

Betadine Antiseptic Liquid Spray should only be applied after at least 10 minutes of rapid cooling of the affected area.

Do not mix with detergents or other chemicals.

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.

Take special care if you currently have or have ever had a kidney problem as using this product may cause toxic levels of iodine to be absorbed into your blood.

- 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 Liquid Spray 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 tauridine are used at the same time.
- Do not use at the same time or immediately after application of ointment 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.

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 Liquid Spray, or any other medicine.

HOW TO USE BETADINE ANTISEPTIC LIQUID SPRAY

Betadine Antiseptic Liquid Spray is for topical use on the skin only.

Hold bottle about 25 cm from skin. Press valve firmly with index finger and spray from any angle to cover desired area. Apply to affected area two or three times per day. Allow to dry. Area may be covered with a secondary dressing and bandaged if desired. Replace cap after use. If actuator clogs, remove and soak with warm water.

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

If you accidentally swallow any Betadine Antiseptic Liquid 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 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 Liquid Spray. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE USING BETADINE ANTISEPTIC LIQUID SPRAY

Things you must 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.

Betadine Antiseptic Liquid Spray can permanently discolour white gold jewellery and it is recommended that this type of jewellery should be removed before using this product.

SIDE EFFECTS

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

If you experience any of the following side effects stop using Betadine Antiseptic Liquid 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, itching and burns on your skin (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) 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.

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 Liquid Spray 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

New Zealand:

<https://nzphvc.otago.ac.nz/reporting>

AFTER USING BETADINE ANTISEPTIC LIQUID SPRAY

Storage

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

Do not store Betadine Antiseptic Liquid Spray 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 solution in 75 mL aerosol can.

Ingredients

Active ingredients:

- Povidone iodine

Inactive ingredients:

- citric acid
- dibasic sodium phosphate
- glycerol
- nonoxinol 9
- purified water
- sodium hydroxide

This medicine does not contain chlorofluorocarbons or other propellants.

Supplier

Betadine Antiseptic Liquid Spray is supplied in Australia by:

Sanofi Consumer Healthcare
87 Yarraman Place, Virginia,
QLD 4014 Australia.
Toll-free: 1800 818 806

Betadine Antiseptic Liquid Spray is supplied in New Zealand by:

sanofi-aventis new zealand limited
Level 8, 56 Cawley Street, Ellerslie,
Auckland 1051, New Zealand
Registration No AUST R 30103

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