Betadine Antiseptic Liquid Spray®

Active ingredient: povidone iodine

Consumer Medicine Information (CMI)

This leaflet provides important information about using Betadine Antiseptic Liquid Spray. 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 Liquid Spray.

Where to find information in this leaflet:

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1. Why am I using Betadine Antiseptic Liquid Spray?

Betadine Antiseptic Liquid Spray contains the active ingredient povidone-iodine.

Betadine Antiseptic Liquid Spray is used to rapidly kill the bacteria commonly responsible for wound and skin infections. For antisepsis of minor cuts, abrasions, minor burns and the treatment of minor skin infections.

2. What should I know before I use Betadine Antiseptic Liquid Spray?

Warnings

BETADINE ANTISEPTIC LIQUID SPRAY IS FOR EXTERNAL USE ONLY.

Do not use Betadine Antiseptic Spray:

- 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.
- If you have a known hypersensitivity to povidone iodine, polyvinylpyrrolidone or to any excipient 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 concurrent lithium therapy or mercury derivatives therapy
- for 4 weeks prior to treatment for cancer of the thyroid.
- if you are pregnant or breastfeeding.

• in children below 2 years of age.

DO NOT USE IF CAP 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. Prolonged use of Betadine Antiseptic Liquid Spray may cause irritation or rarely, severe skin reactions.

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 other 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.

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 <u>6</u>. Are there any side effects?

Pregnancy and breastfeeding

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

Betadine Antiseptic Liquid Spray 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 Liquid Spray and affect how it works.

- 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 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 Liquid Spray.

4. How do I use Betadine Antiseptic Liquid Spray?

How much to use

 Hold bottle about 25 cm from skin. Press valve firmly with index finger and spray from any angle to cover desired area.

When to use Betadine Antiseptic Liquid Spray

 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.

How to use Betadine Antiseptic Liquid Spray

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

If you use too much Betadine Antiseptic Liquid Spray

If you think that you have used too much Betadine Antiseptic Liquid, 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.

You may need urgent medical attention

5. What should I know while using Betadine Antiseptic Liquid Spray?

Things you should do or know

- 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.
- 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

Allergic reactions	Call your doctor
 Difficulty breathing or swallowing Rash, swelling of face, lips, throat, or tongue Itching and burns or small blisters on your skin 	straight away, or go straight to the Emergency Department at your nearest hospital if you
Thyroid related	notice any of
 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. 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 osmolarity Kidney failure (symptoms include difficulty in urinating, thirst and a dry mouth, and pain in one side of your back) has been reported. 	these serious side effects.

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 Liquid Spray 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 <u>www.tga.gov.au/reporting-problems</u>.

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 Liquid Spray contains

Active ingredient	Povidone iodine
(main ingredient)	
Other ingredients	citric acid
(inactive ingredients)	dibasic sodium phosphate
	glycerol
	nonoxinol 9
	purified water
	sodium hydroxide
Potential allergens	N/A

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

What Betadine Antiseptic Liquid Spray looks like

Betadine Antiseptic Liquid Spray is a brown solution in a 75 mL aerosol can.

(AUST R 30103)

Who distributes Betadine Antiseptic Liquid Spray

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 New Zealand Toll free (NZ): 0800 283 684

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