

Betadine Sore Throat Gargle®

Active ingredient: *povidone iodine*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Betadine Sore Throat Gargle. **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 Sore Throat Gargle.**

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1. Why am I using Betadine Sore Throat Gargle?

Betadine Sore Throat Gargle contains the active ingredient povidone-iodine.

Betadine Sore Throat Gargle is a concentrated anti-bacterial formula used as an aid in the treatment of sore throats.

It contains alcohol (30.5% w/v.)

2. What should I know before I use Betadine Sore Throat?

Warnings

BETADINE SORE THROAT GARGLE MUST NOT BE SWALLOWED.

Do not use Betadine Sore Throat Gargle 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.
- you have a severe sore throat accompanied by fever, headache, nausea or vomiting or any sore throat persisting for more than 2 days may be serious. In such cases consult a doctor.
- you have a known hypersensitivity to povidone iodine, iodine, polyvinylpyrrolidone or to any excipient. If irritation, redness or swelling develops, discontinue treatment and consult a doctor.
- you have a known to have thyroid disease including goiter, thyroid nodules, or other thyroid diseases (especially elderly patients) as there may be a risk of developing hyperthyroidism from the administration of large amounts of iodine.
- The maximum treatment duration of 14 days should not be exceeded. Prolonged treatment could result in a normal microbial flora imbalance in the oral cavity with a risk of bacterial or fungal dissemination.

- it should not be used for 4 weeks prior to treatment for cancer of the thyroid
- you are pregnant or breastfeeding.

Not for use on children 6 years and under

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

Check with your doctor if you:

- have any other medical conditions
- take any medicines for any other conditions
- 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.

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

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

Check with your doctor if you are pregnant or intend to become pregnant.

During pregnancy and lactation, povidone-iodine preparations should only be used if strictly prescribed by the doctor and its use should be kept to the absolute minimum. Absorbed iodine can cross the placental barrier and can be secreted in breast milk.

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

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 Sore Throat Gargle and affect how it works.

- Lithium (for depression) can interact with Betadine Sore Throat Gargle 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.
- Concomitant use with mercury derivatives is contraindicated. Mercurial and iodine antiseptics can create a caustic complex during their concomitant use. The interaction depends on the organomercurial stability at cutaneous level and on the individual sensitivity.
- The joined use of a hydrogen-peroxide mouthwash and povidone-iodine mouthwash can lead to a weakening of the effects of both substances.

- Do not use concomitantly or immediately after application of octenidine containing antiseptics in same or adjacent sites, as this may lead to transient dark discoloration in the areas involved.
- 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.

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 Sore Throat Gargle.

4. How do I use Betadine Sore Throat Gargle?

How much to use

- **This gargle must be diluted before use; a convenient measure is included in the pack.**

Dilute 1mL to 20mL with water using the measure provided (or alternatively add 20 drops to 20mL water) and gargle for 30 seconds.

- This product is not intended for routine use as a breath freshener or mouthwash.
- Betadine Sore Throat Gargle will not permanently stain teeth, skin or natural fabrics.

When to use Betadine Sore Throat Gargle

- The maximum treatment duration of 14 days should not be exceeded. Prolonged treatment could result in a normal microbial flora imbalance in the mouth

If you use too much Betadine Sore Throat Gargle

If you think that you have used too much Betadine Sore Throat Gargle, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- New Zealand 0800 POISON or 0800 764766), or
- 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 Sore Throat Gargle?

Things you should do

- Tell your doctor if you are due to have a thyroid test since absorption of iodine from povidone-iodine solution may interfere with thyroid function tests.
- 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.
- **Avoid inhalation.**

- **Avoid contact with the eyes.**
- Remind any doctor, dentist or pharmacist you visit that you are using Betadine Sore Throat Gargle.

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 cool dry place where temperature stays below 25°C
- Do not heat the solution.

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.

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
<ul style="list-style-type: none"> • Breathing related • coughing • difficulty breathing • wheezing • 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<p>Allergic reactions</p> <ul style="list-style-type: none"> • difficulty breathing or swallowing, a rash, swelling of the face, lips, throat or tongue. <p>Thyroid related</p> <ul style="list-style-type: none"> • 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. 	<p>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.</p>

Serious side effects	What to do
<p>Blood related</p> <ul style="list-style-type: none"> 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 <p>Kidney related</p> <ul style="list-style-type: none"> kidney failure (symptoms include difficulty in urinating, thirst and a dry mouth, and pain in one side of your back) has been reported. 	

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

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

New Zealand:

<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 Sore Throat Gargle contains

Active ingredient (main ingredient)	Povidone iodine
Other ingredients (inactive ingredients)	citric acid monohydrate dibasic sodium phosphate dodecahydrate ethanol glycerol menthol methyl salicylate purified water sodium hydroxide
Potential allergens	N/A

This medicine does not contain lactose, sucrose, gluten, tartrazine or any other azo dyes.

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

What Betadine Sore Throat Gargle looks like

A brown solution in 15 or 40 mL bottles.

(AUST R 29566)

(TT50-0462/11)

Who distributes Betadine Sore Throat Gargle?

Betadine Sore Throat Gargle is supplied in Australia by:

Sanofi Consumer Healthcare

87 Yarraman Place, Virginia,

Qld 4014 Australia.

Toll-free: 1800 818 806

Betadine Sore Throat Gargle is supplied in New Zealand by:

sanofi-aventis new zealand limited

New Zealand

Toll free (NZ): 0800 283 684

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