

BETADINE SORE THROAT GARGLE®

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

Consumer Medicine Information

WHAT IS IN THIS LEAFLET

This leaflet answers some common questions about Betadine Sore Throat Gargle.

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 Sore Throat Gargle 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 Sore Throat Gargle immediately and tell a doctor or pharmacist.

WHAT BETADINE SORE THROAT GARGLE IS USED FOR

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

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

Always read the label.

It contains alcohol (30.5% w/v.)

Do not to heat the solution.

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

BEFORE YOU USE BETADINE SORE THROAT GARGLE

BETADINE SORE THROAT GARGLE MUST NOT BE SWALLOWED.

When you must not take it

- 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.
- known hypersensitivity to iodine or povidone. If irritation, redness or swelling develops, discontinue treatment and consult a doctor.
- if 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.
- it should not be used for 4 weeks prior to treatment for cancer of the thyroid
- not recommended during pregnancy or breastfeeding.

- on infants under 6 months of age.
- DO NOT USE IF CAP SEAL IS BROKEN OR AFTER EXPIRY DATE.

Keep out of the reach of children.

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.

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

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 Sore Throat Gargle to affect the function of the thyroid gland. Therefore, concurrent use should be avoided.

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.

HOW TO TAKE BETADINE SORE THROAT GARGLE

Betadine Sore Throat Gargle must be diluted before use. 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.

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 Sore Throat Gargle. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

WHILE YOU ARE TAKING BETADINE SORE THROAT GARGLE

Things you must 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.

SIDE EFFECTS

Like all medicines, Betadine Sore Throat Gargle may cause side effects, although not everybody gets them.

If you experience any of the following side effects stop using Betadine Sore Throat Gargle 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**

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 Sore Throat Gargle 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 TAKING BETADINE SORE THROAT GARGLE

Storage

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

Do not store Betadine Sore Throat Gargle 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

Unused 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 15 or 40 mL bottles.

Ingredients

Active ingredients:

- Povidone iodine

Inactive ingredients:

- citric acid monohydrate
- dibasic sodium phosphate dodecahydrate
- ethanol
- glycerol
- menthol
- methyl salicylate
- purified water
- sodium hydroxide

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

Supplier

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

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