

Package leaflet: Information for the user

Betadine Gargle and Mouthwash 10mg/ml Oral Solution Povidone Iodine

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Betadine Gargle and Mouthwash carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice
- You must contact your doctor if your symptoms worsen or do not improve
- If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, stop using Betadine Gargle and Mouthwash straightaway and tell your doctor or pharmacist.

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1. What Betadine Gargle and Mouthwash 10mg/ml Oral Solution is and what it is used for

Betadine Gargle and Mouthwash contains povidone iodine which kills a wide range of germs including bacteria, viruses, fungi, spores and simple organisms.

Betadine Gargle and Mouthwash is used for the treatment of acute infections of the lining of the mouth and throat, for example, inflammation of the gums (gingivitis) and mouth ulcers. For cleansing the mouth (oral hygiene) before, during and after dental and mouth surgery.

2. Before you use Betadine Gargle and Mouthwash 10mg/ml Oral Solution

Do not use Betadine Gargle and Mouthwash 10mg/ml Oral Solution:

- if you are allergic (hypersensitive) to povidone iodine or any of the other ingredients listed
- 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 Gargle and Mouthwash in these circumstances can further affect the function of your thyroid
- if you are currently having lithium therapy for depression as this type of medicine can interact with Betadine Gargle and Mouthwash to affect the function of your thyroid
- on children of 6 years and under.

Talk to your doctor or pharmacist before using Betadine Gargle and Mouthwash 10mg/ml Oral Solution

- if your skin is broken (for example, due to a burn) as using Betadine Gargle and Mouthwash in these circumstances may cause toxic levels of iodine to be absorbed into your blood
- if you currently have or have ever had a kidney problem as using Betadine Gargle and Mouthwash in these circumstances may cause toxic levels of iodine to be absorbed into your blood
- when you know you are due to have a thyroid, faeces (stool) or urine test as Betadine Gargle and Mouthwash may affect the results.

Using other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription, before you use Betadine Gargle and Mouthwash.

Pregnancy and breastfeeding

If you know or think you might be pregnant, or are breastfeeding, talk to your doctor or pharmacist before using Betadine Gargle and Mouthwash or any other medicine.

3. How to use Betadine Gargle and Mouthwash 10mg/ml Oral Solution

Use orally (in your mouth) as a gargle and mouthwash. **Betadine Gargle and Mouthwash should NOT be swallowed.**

Adults, the elderly and children over 6 years of age: Use undiluted with an equal volume of warm water. Gargle or rinse with up to 10 ml of Betadine Gargle and Mouthwash for up to 30 seconds without swallowing. Repeat up to four times daily, for up to 14 days in a row, or as directed by your doctor or pharmacist. Do not use for more than 14 days.

Must NOT be used in children of 6 years and under.

IF YOU ACCIDENTALLY SWALLOW ANY BETADINE GARGLE AND MOUTHWASH SEEK MEDICAL ADVICE IMMEDIATELY, TAKING THE BOTTLE WITH YOU.

Betadine Gargle and Mouthwash can permanently discolour white gold jewellery and it is recommended that this type of jewellery should be removed before using Betadine Gargle and Mouthwash.

If you have any further questions on the use of Betadine Gargle and Mouthwash ask your doctor or pharmacist before use.

4. Possible unwanted effects

Like all medicines, Betadine Gargle and Mouthwash can cause unwanted effects, although these are uncommon.

Allergic-type reactions, including a rash or difficulty in breathing, have been reported uncommonly with products containing povidone iodine (the active ingredient in Betadine Gargle and Mouthwash). Although rare, Betadine Gargle and Mouthwash could also cause itching and burns on your skin.

Applying very large amounts of medicines containing povidone iodine, or using such products over a long period of time, can occasionally cause thyroid disorders (symptoms of which include weight loss, increased appetite and sweating or lacking energy and weight gain). Other effects that have been reported are increased amounts of acid in your blood (the main symptoms are shortness of breath, confusion and lethargy) and kidney failure (symptoms include difficulty in urinating, thirst and a dry mouth and pain in one side of your back).

Should you suffer from any of these unwanted effects, or if you notice any unwanted effects not listed in this leaflet, stop using Betadine Gargle and Mouthwash straightaway and tell your doctor or pharmacist.

5. How to store Betadine Gargle and Mouthwash 10mg/ml Oral Solution

Keep out of the reach and sight of children.

Do not use Betadine Gargle and Mouthwash after the expiry date stated on the label.

Store below 25°C. Protect from light.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Further information

What Betadine Gargle and Mouthwash 10mg/ml Oral Solution contains

The active substance is povidone iodine. Each ml of Betadine Antiseptic Paint contains 10 mg povidone iodine.

The other ingredients are: Glycerol (E422), menthol, methyl salicylate, ethanol, saccharin sodium (E954) and purified water.

What Betadine Gargle and Mouthwash 10mg/ml Oral Solution looks like and contents of the pack

Betadine Gargle and Mouthwash is a liquid (oral solution) and is sold in a glass (amber soda-lime-silica) bottle, with plastic (polypropylene) cap, containing 250ml of product.

Marketing Authorisation Holder and Manufacturer

The name and address of the marketing authorisation holder is Napp Pharmaceuticals Ltd, Cambridge Science Park, Milton Road, Cambridge, CB4 0GW, UK.

The name and address of the manufacturer is SSL International plc, Whitehouse Industrial Park, Traynor Way, Peterlee, Durham. SR8 2RU, UK.

This leaflet was last approved in July 2019.