



CLIENT: MUNDI PHARMA

PROJECT: BETADINE MOUTH WASH - LEAFLET (EN/AR)

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Package leaflet: Information for the user

BETADINE® 1% w/v Mouthwash & Gargle

Povidone-iodine

MUNDIPHARMA
Pharmaceuticals Ltd.



Read all this leaflet carefully before you start using this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, or nurse.
- If you get any side effects, talk to your doctor, pharmacist, or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What BETADINE® Mouthwash & Gargle is and what it is used for
2. What you need to know before you use BETADINE® Mouthwash & Gargle
3. How to use BETADINE® Mouthwash & Gargle
4. Possible side effects
5. How to store BETADINE® Mouthwash & Gargle
6. Contents of the pack and other information

1. What BETADINE® Mouthwash & Gargle is and what it is used for?

BETADINE® Mouthwash & Gargle is an antiseptic Mouthwash & Gargle solution. It kills bacteria, fungi, spores, yeasts, protozoa and viruses.

It is indicated for the treatment of infected inflammatory conditions of the mouth and pharynx including stomatitis, gingivitis, aphthous ulcers, pharyngitis, tonsillitis, monilial infections, common colds and influenza.

- As a prophylactic during and after surgery e.g. after tonsillectomy and dental procedures.
- Routine use to promote oral hygiene.

2. What you need to know before you use BETADINE® Mouthwash & Gargle

Do not use BETADINE® Mouthwash & Gargle:

- if you are allergic to Povidone-iodine or any of the other ingredients of this medicine (listed in section 6).
- in patients hypersensitive to iodine or any other of the ingredients listed in section 6.
- in patients with thyroid disorders (in particular nodular colloid goiter, endemic goiter and Hashimoto's thyroiditis).
- in patients taking lithium.
- Before, during and after radio-iodine administration.
- in patients using products containing mercury.
- in children under 6 years of age.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using **BETADINE® Mouthwash & Gargle**

- Special caution is needed when regular applications to broken skin are made to patients with pre-existing renal insufficiency.

- Thyroid function tests may be affected using products containing iodine.
- Contamination with Povidone-iodine of several tests for detecting occult blood in faeces or blood in urine may produce false-positive results.
- With false teeth, braces etc., the material from which they are made can sometimes become discoloured. It is therefore recommended to remove false teeth, braces etc. from the mouth before using **BETADINE® Mouthwash & Gargle**.

Children and adolescents

Do not use in children under 6 years of age.

Other medicines and BETADINE® Mouthwash & Gargle

- Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.
- The concomitant use of wound-treatment preparations containing a so-called enzymatic component leads to a weakening of the effects of both substances. Products containing mercury, silver, hydrogen peroxide, and tauridine may interact with povidone-iodine and should not be used concomitantly.
- Simultaneous use with mercury products may lead to the formation of a substance, which can damage the mucosa.

- Using this treatment may interfere with tests of thyroid function and can make a planned treatment of the thyroid with iodine impossible.
- After the end of the treatment, 4 weeks should be allowed before a new scintigram is carried out.
- Several types of tests for detecting occur (not visible) blood in faeces or blood in urine may be affected (i.e. produce false-positive results).
- Povidone-iodine products when used before or after application of octenidine may lead to transient dark discolourations at the application site.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. Povidone iodine passes into the placenta and is secreted in breast milk. Povidone iodine use should be avoided unless the potential benefit to the mother justifies the potential risk to the foetus and neonate or if a safer alternative is unavailable. During pregnancy and lactation **BETADINE® Mouthwash & Gargle** should only be used under medical prescription.

Fertility

There are limited human fertility data for Povidone iodine. No data are available on fertility outcomes

Driving and using machinery

No influence has been reported.

3. How to use BETADINE® Mouthwash & Gargle

Always use this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. For Oromucosal use.

Adults, Elderly and Children over 6 years of age:

- Use undiluted or diluted with two parts of water.
 - For prophylactic use, the solution should be allowed to act in the mouth for a minimum of 30 seconds.
 - With existing lesions the mouth should be rinsed with the solution for two minutes, four times a day, especially after meals.
 - Do not swallow.
- If there is no improvement of symptoms after 2-5 days of regular use of the product, consult your doctor.

If you use more BETADINE® Mouthwash & Gargle than you should

What to do in the event of accidental ingestion of **BETADINE® Mouthwash & Gargle?** In the event of accidental or deliberate ingestion of large quantities of **BETADINE® Mouthwash & Gargle**, contact immediately your doctor or nearest hospital.

Symptoms: Overdose can cause symptoms like metallic taste in the mouth, increased salivation, burning or pain in the throat or mouth, irritation and swelling in the eyes, breathing difficulties due to pulmonary oedema, skin reactions, gastrointestinal upset and diarrhoea. Metabolic acidosis, hypernatraemia and renal impairment may occur. Systemic toxicity may result in renal impairment (including anuria), tachycardia, hypotension, circulatory failure, oedema of glottis resulting in asphyxia, or pulmonary oedema, seizures, fever and metabolic acidosis. Hyperthyroidism or hypothyroidism may also develop.

Therapy: Symptomatic and supportive treatment should be provided, with special attention to electrolyte balance and renal and thyroid function.

For severe hypotension, intravenous fluid should be administered; vasopressors should be added if necessary. Endotracheal intubation may be required if caustic injury to the upper airway results in significant swelling and oedema.

Vomiting should not be induced. Patient should be maintained in a position to keep the airways open and prevent aspiration (in case of vomiting). If the patient is not vomiting and can tolerate oral feeding, then ingestion of starchy food (e.g. potato, flour, starch, bread) may help convert iodine to less toxic iodide. If no signs of bowel perforation are present, irrigation of the stomach with starch solution via nasogastric tube may be utilized (gastric effluent will turn dark blue-purple and the colour can be used as a guide in determining when lavage can be terminated). Haemodialysis effectively clears iodine and should be employed in severe cases of iodine poisoning particularly if renal failure is present. Continuous venovenous

haemodiafiltration is less effective than haemodialysis.

In case of thyroid dysfunction, treatment with povidone-iodine should be discontinued.

If you forget to use BETADINE® Mouthwash & Gargle

If you forget to use your medication, use it as soon as you remember unless it's time for the next application. Then follow the original instructions for use. Do not take a double dose to make up for a forgotten dose.

If you stop using BETADINE® Mouthwash & Gargle

The usual period of treatment (unless otherwise advised by your doctor) could last for about 14 days. The duration of treatment is decided by your doctor according to the indications of your problem. If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Very rarely, irritation of the lining of the mouth and sensitivity reactions may occur. The long-term use of Povidone-iodine can lead to an excessive absorption of iodine and may produce systemic adverse effects such as metabolic acidosis, hypernatraemia and impairment of renal function.

Should you experienced any of the above side effects or any other unusual effects, stop using the medicine and consult your doctor or pharmacist at once.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store BETADINE® Mouthwash & Gargle

- Keep this medicine out of the sight and reach of children.
- Do not use this medicine after the expiry date which is stated on the label and the carton after the EXP. The expiry date refers to the last day of that month.
- Store this product at or below 25°C, in the packaging that it comes in.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What BETADINE® Mouthwash & Gargle contains

- The active substance is Povidone-iodine
- The other excipients are Glycerol, Menthol, Methyl Salicylate, Ethanol, Saccharin Sodium, Purified Water.

What BETADINE® Mouthwash & Gargle looks like and contents of the pack
BETADINE® Mouthwash & Gargle is a yellow brown liquid supplied in beige polyethylene container with a polyethylene-spraying insert fitted with polypropylene cap. The content of the product is 50ml, 60ml, 120ml, 125ml and 250ml and is enclosed in printed carton.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Mundipharma Pharmaceuticals Ltd
13 Othellos str. Dhali Industrial Zone,
2540 Nicosia,
Cyprus

This leaflet was last revised in 08/2022.

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