

**Patient Leaflet According to the Pharmacists' Regulations (Preparations) - 1986**

This medicine is sold with a doctor's prescription only

**Betadine® Gargle**  
**Concentrated Solution**  
**Gargle and Mouthwash**

**Active ingredient:**

7.5% Povidone Iodine (equivalent to 0.75% available iodine).

For a list of the other ingredients, please see section 6.

**Read this entire leaflet carefully before using this medicine.**

This leaflet contains concise information about the medicine. If you have any further questions, refer to your doctor or pharmacist.

This medicine was prescribed for your treatment, do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

**1. What is the medicine intended for?**

This medicine is intended for infections in the mouth and throat:

- For the treatment of infections/inflammations in the mouth, throat and gums, caused by fungi, bacteria or viruses.
- For the treatment of mouth and throat injuries.
- For disinfection of the oral cavity before surgeries.
- Prevention of radiotherapy-induced mouth inflammations and ulcers.

**Therapeutic group:**

Antiseptics

**2. Before using the medicine**

**Do not use the medicine if:**

- Do not use if you are sensitive (allergic) to the active ingredient, to iodine, or to any of the other ingredients this medicine contains (for a list of the other ingredients, please see section 6).
- Do not use if you suffer from overactive thyroid gland (hyperthyroidism) or other thyroid disorders.
- Do not use if you suffer from dermatitis herpetiformis (Duhring disease), which is an autoimmune disease with blisters.
- Do not use before and after treatment with radioactive iodine (until conclusion of the treatment).

**Special warnings regarding the use of this medicine:**

- Inform your attending doctor if you suffer from latent thyroid gland diseases (especially in elderly patients) particularly with prolonged use (longer than 14 days) or use on a large area.
- When using in the throat, be careful not to inhale the solution (aspiration). This may lead to breathing problems and even inflammation of the lungs. Be extra careful when using with intubated patients.
- The active ingredient has oxidation properties that may cause corrosion and discoloration of metals (e.g. dentures, braces).
- If the solution stains textiles, the stain can generally be removed with lukewarm water and soap.
- Protein and organic substances such as blood or pus may reduce the activity of the active ingredient.

- Use of the medicine may distort various tests and treatments, particularly those testing the thyroid gland and are connected to iodine. It is recommended to wait 1 - 2 weeks after discontinuation of the treatment with Betadine.
- There may be errors in various medical tests results, such as certain tests for determination of hemoglobin or glucose in stool or urine.

**Before using the medicine, consult your doctor if** you suffer or have suffered in the past from thyroid gland disorders, since there is a risk of developing an overactive thyroid gland (hyperthyroidism).

**If you are taking or have recently taken any other medicines, including non-prescription medicines and nutrition supplements, please tell your doctor or pharmacist.** Especially inform your doctor or pharmacist if you are taking the following medicines (it should be noted that the following list mentions the active ingredients of the medicines. If you are unsure whether you are using one of these medicines, please consult with your doctor or pharmacist):

- Hydrogen peroxide, enzymatic, silver or taurolidine containing wound healing agents or antiseptics: concurrent use may reduce the effect of the preparations.
- Do not use together with taurolidine, mercury-containing preparations or antiseptics containing octenidine.
- Lithium: avoid long-term use, especially on a large area, in patients taking lithium.

#### **Pregnancy and breastfeeding:**

- If you are pregnant, plan to become pregnant or if you are breastfeeding, consult your doctor before using the medicine.
- If you use the medicine while pregnant and/or breastfeeding (after careful diagnosis and in limited quantities), consult your doctor regarding monitoring tests of the thyroid gland functions in the mother and the baby.

#### **Use in children:**

- The medicine is not intended for use in babies under 6 months of age.
- The use in children over 6 months of age is permitted only if they can use the medicine according to the instructions, i.e to avoid swallowing the solution.

#### **Tests and follow-up:**

- Thyroid gland functions should be monitored as necessary.
- There may be errors in various medical tests results, such as certain tests for determination of hemoglobin or glucose in stool or urine.

#### **Important information about some of the medicine's ingredients:**

Before dilution, the solution contains approximately 30% ethanol (alcohol).

### **3. How to use this medicine?**

Always use according to the doctor's instructions. Check with your doctor or pharmacist if you are not sure regarding the dosage and the manner of treatment. The dosage and the manner of treatment will be determined by the doctor only.

#### **The standard dosage is usually:**

For the treatment of infections/inflammations in the gums and/or mouth and throat, and for treatment of throat injuries:

- Dilute 2 to 4 caps in approximately 125 mL (about half a glass) of water.
- Wash or gargle for at least 30 seconds every 1 - 4 hours, until there is an improvement.

Prevention of radiotherapy-induced mouth inflammations and ulcers:

Dilute 4 caps in approximately 125 mL (about half a glass) of water. Use several times daily, after meals. Keep the solution in your mouth for approximately 3 minutes each time.

For disinfection of the oral cavity before surgeries:

Gargle the solution for at least 30 seconds in the area intended for surgery.

**Do not exceed the recommended dose.**

**Directions for use:**

- For mouth and throat use.
- The solution is intended for gargling and as a mouthwash. Wash and/or gargle and then spit out.
- If the solution is to be diluted, dilute just prior to use.
- Do not dilute in hot water.
- Do not swallow.
- Do not use directly from the bottle.
- Temporarily remove dentures, braces etc. from your mouth, in order to allow better accessibility to the gums and oral mucous and to prevent discoloration of the accessories.
- Do not use together with other gargling solutions.

Duration of the treatment:

The duration of the treatment depends on the intended use. Continue to use Betadine as long as signs of infection persist and/or a risk of infection is present.

If there is no improvement in your condition, or if there is any deterioration, refer to your doctor.

**If you have accidentally used a higher dosage** or if someone has swallowed the solution, refer immediately to a doctor or a hospital emergency room and bring the medicine package with you. Overdose symptoms relating to swallowing of iodine include: abdominal pain and cramping, nausea, vomiting, diarrhea, dehydration, hypotension potentially leading to shock, edema of the glottis, tendency to bleed, cyanosis, kidney damage potentially leading to inability to urinate, tingling, fever and pulmonary edema. In prolonged use of an overdose: overactive thyroid gland symptoms such as tachycardia (rapid heartbeat), restlessness, tremor, headache. In you, accidentally swallow a large quantity of the solution, alcohol-poisoning symptoms may develop.

Continue the treatment as recommended by your doctor.

Do not use or take medicines in the dark! Check the label and the dose each time you take or use a medicine. Wear glasses if you need them.

If you have further questions concerning the use of the medicine, consult the doctor or pharmacist.

## **4. Side effects**

Like any medicine, the usage may cause side effects in some users. Do not be alarmed while reading the list of side effects, you may not suffer from any of them.

**Stop using the medicine and go to your doctor immediately if a severe allergic reaction occurs (anaphylactic reaction), which can include also symptoms such as:** blood pressure drop, dizziness, nausea, breathing difficulties.

Additional side effects:

*Rare side effects (appear in 1-10 users out of 10,000):* hypersensitivity (allergy); hypersensitivity reactions of the skin (e.g. contact allergic inflammation, which can also be a delayed reaction, with symptoms of pruritus, redness, blistering).

*Very rare side effects (appear in less than 1 out of 10,000 users):* angioedema; overactive thyroid gland (hyperthyroidism) with symptoms such as tachycardia (rapid heartbeat) or restlessness.

*Side effects of unknown frequency (effects whose frequency has not yet been determined):* underactive thyroid gland (hypothyroidism); inflammation of the lungs (aspiration-related); effects that may occur particularly from excessive absorption of iodine: electrolyte imbalance, metabolic acidosis, kidney failure, abnormal osmolarity of the blood.

If a side effects appears, if one of the side effects worsens, or if you suffer from a side effect not mentioned in the leaflet, consult your doctor.

#### Reporting side effects:

Side effects may be reported to the Ministry of Health by clicking on the link "Report on side effects following medicinal treatment" on the homepage of the Ministry of Health website ([www.health.gov.il](http://www.health.gov.il)) which leads you to the online form for reporting side effects, or by entering the link:

<https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

## 5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a safe place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) stated on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store below 25°C.
- After the first opening, the product may be used within 12 months, but no later than the expiry date imprinted on the package.

## 6. Additional information

### • In addition to the active ingredients, the solution also contains:

Ethanol, glycerol, disodium phosphate, saccharin sodium, methyl salicylate, citric acid, sodium hydroxide, levomenthol, purified water.

### • What does the medicine look like and what does the package contain?

Reddish-brown solution in a bottle with a cap. The bottle contains 100 or 120 mL.

Not all package sizes may be marketed.

**Registration holder:** Rafa Laboratories Ltd., P.O Box 405, Jerusalem 9100301.

**Manufacturer:** Mundipharma GmbH, Germany.

**Medicine registration number in the National Medicines Registry of the Ministry of Health:** 160-23-35134

This leaflet was checked and approved by the Ministry of Health in March 2018.

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