

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

This medicine is sold without a doctor's prescription

Betadine® Topical Spray

Active ingredient:

Povidone Iodine 2.5% (equivalent to 0.25% available iodine).

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

Read this entire leaflet carefully before using the medicine.

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

Use the medicine according to the instructions in the dosage section of this leaflet. Consult your pharmacist if you require additional information.

Refer to your doctor if the symptoms get worse or do not improve.

1. What is the medicine intended for?

This medicine is intended for skin disinfection:

- For treatment and prevention of skin infections as a result of burns, cuts and scrapes.
- For preventive treatment of wounds that might become infected, e.g.: after surgery or stitches.

Therapeutic group:

Antiseptics

2. Before using the medicine

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient, to iodine, or to any of the other ingredients this medicine contains (for the list of the other ingredients, please see section 6).
- You suffer from overactive thyroid gland (hyperthyroidism manifested by increase in heart rate and restlessness), or from any other thyroid gland disorder.
- You suffer from dermatitis herpetiformis (Duhring's Disease), which is an autoimmune disease with blisters.
- Do not use together with mercury-containing products or antiseptics based on octenidine.
- Do not use before and after treatment with radioactive iodine (until completion of the treatment).
- Do not use before tests with radioactive iodine (thyroid gland scintigraphy).

Special warnings regarding the use of this medicine:

- Do not inhale the spray mist.
- Do not spray into eyes or on areas around the eyes.
- The spray mist is flammable! Avoid proximity to fire (when spraying and storing).
- Do not expose to temperatures exceeding 50°C.
- Before use of electric devices (such as electrocautery), wait until the spray mist has completely dissipated.
- If the spray has stained textiles, the stain can generally be removed with warm water and soap.
- For babies under the age of 6 months, the medicine should only be used according to a doctor's instructions. If the doctor decides on use of the medicine, thyroid gland function should be monitored.
- The active ingredient has oxidation properties that may cause corrosion and discoloration of metals.
- Protein and organic substances such as blood or pus may reduce the activity of the active ingredient.
- Use of this medicine may reduce iodine absorption by the thyroid gland; this may affect various thyroid gland function tests and thyroid gland treatment. Wait 1 - 2 weeks after discontinuation of Betadine usage.

- There may be distortions in various medical test results, such as certain stool or urine tests for determination of hemoglobin or glucose.
- Extensive treatment of burns on large skin surfaces may cause electrolyte imbalance and an associated impairment of kidney function.

Before using the medicine, consult your doctor if you suffer or have suffered in the past from thyroid gland problems (especially elderly patients) or goiter. Prolonged use of the medicine or on large skin surfaces should be according to a doctor's instructions only. After the end of treatment (up to 3 months after treatment completion), thyroid gland function and early symptoms of hyperthyroidism should be monitored by the doctor.

Drug interactions:

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 in the medicines. If you are unsure whether you are using one of these medicines, please consult with your doctor or pharmacist):

- Hydrogen peroxide, antiseptics or wound treatment products containing silver, enzymes or taurolidine: concurrent use might reduce the effect of the products.
- Do not use together with mercury-containing products: concurrent use may cause the formation of a caustic (burning) compound (mercury iodide).
- Do not use together with octenidine-containing products: concurrent use may cause temporary dark skin discolorations.
- Do not use together with products containing taurolidine (a chemotherapeutic agent for treatment of bacterial and fungal infections): concurrent use may lead to the formation of formic acid which may cause extensive burning of the skin.
- Lithium: if you are taking lithium, Betadine spray should only be used for a short period and on small skin surfaces (due to concern that large amounts of iodine may be absorbed into the body).

Pregnancy and breastfeeding:

- If you are pregnant, plan to become pregnant or if you are breastfeeding, consult your doctor before using the medicine.
- Use of the medicine during pregnancy and/or while breast-feeding is permitted only upon a doctor's approval, for short periods, while monitoring thyroid gland function of the mother and infant. Treatment should be restricted to a short period only. Iodine passes through the placenta to the fetus and is also secreted into breast milk.
- Accidental oral ingestion of the medicine by the breast-fed infant as a result of contact with the treated skin area of the nursing mother, must be avoided.

Use in Children:

- For babies under the age of 6 months, the medicine should only be used according to a doctor's instructions. If the doctor decides on use of the medicine, thyroid gland function should be monitored.
- Swallowing of the medicine by children must be avoided.

Tests and follow up: In certain cases, monitoring of thyroid gland functions may be necessary.

3. How to use this medicine?

Use the medicine as described in the leaflet. You should check with your doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The spray is intended for external use only.

The standard dosage is usually:

The dosage will be determined according to the size of the area to be treated.

Spray once to several times daily on the treated area until it is covered with a yellow-brown layer of the powder. If the color fades, spray again.

Dosage in babies under 6 months of age: the dosage and the manner of treatment will be determined by the doctor.

Do not exceed the recommended dose.

Directions for use:

- Shake the aerosol can well before use.
- Hold the can upright and spray on the treated area from a distance of about 15 cm.
- The spray gas dissipates rapidly and the cold sensation experienced upon application, disappears within a short time.
- The spray forms a dry film on the treated area which can be easily washed off.
- If necessary, the treated area can be bandaged.
- Avoid contact with the eyes.

If you have accidentally used a higher dosage or if someone has swallowed the medicine, go to a doctor or a hospital emergency room and bring the medicine package with you.

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 your doctor or pharmacist.

4. Side Effects

Like any medicine, the use of Betadine 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.

Rare side effects (appear in 1-10 users out of 10,000): hypersensitivity (allergy); hypersensitivity reactions of the skin (with symptoms such as itchiness, redness, blistering).

Very rare side effects (appear in less than 1 user out of 10,000): acute allergic general reaction (anaphylactic reaction) which usually includes: blood pressure drop, dizziness, nausea, breathing difficulties;

Angioedema (allergic, painful swelling of skin and mucous membranes);

Overactive thyroid gland 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; electrolyte imbalance, metabolic acidosis, kidney failure, abnormal osmolarity of the blood. These side effects may occur as a result of excessive absorption of iodine and/or use for a prolonged period.

Side effects and drug interaction in children:

Parents must inform the attending doctor of any side effect as well as any additional medicine given to the child. See above for detailed side effects and drug interactions.

If a side effect 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) which leads you to the online form for reporting side effects, or by entering the link: <https://sideeffects.health.gov.il/>

5. How to store the medicine?

- Avoid poisoning! This medicine, and any other medicine, must be stored in a closed 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.
- Flammable! Keep away from fire sources.
- Do not expose to temperatures exceeding 50°C (see also warnings).

6. Additional information

- **In addition to the active ingredients, the medicine also contains:**

Isopropyl myristate, n-pentane, gas propellant (mixture of propane, butane and isobutane).

- **What does the medicine look like and what does the package contain?**

Reddish-brown skin spray in 30 gram or 80 gram aluminum can (not all package sizes may be marketed).

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

Manufacturer: Mundipharma Ltd., Nicosia, Cyprus

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