

BETADINE® MOUTHWASH / GARGLE

Mundipharma Middle East FZ LLC

Active substance: Povidone-iodine (PVP-I) 1% w/v

1- What is BETADINE® Mouthwash/Gargle and what is that used for ?

What is BETADINE® Mouthwash/Gargle?

BETADINE® Mouthwash/Gargle is a broad-spectrum microbicide solution for use on the mucous membranes of the mouth and throat.

What does BETADINE® Mouthwash/Gargle contain?

- Active substance : Povidone-iodine 1% w/v
- Inactive ingredients: Glycerol; Menthol; Methyl Salicylate; Ethanol; Saccharin Sodium and Purified Water.

What is BETADINE® Mouthwash/Gargle used for?

- Adjunct 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.

BETADINE® Mouthwash/Gargle kills bacteria, fungi, spores yeasts, protozoa, and viruses

2- Packing sizes:

BETADINE® Mouthwash/Gargle is supplied in polyethylene container, fitted with polypropylene cap, enclosed in a printed carton.

BETADINE® Mouthwash/Gargle is available in packs of 120 ml, 125 ml, 250 ml.

Not all the pack sizes may be marketed.

3- Before using BETADINE® Mouthwash/Gargle:

Contraindications:

- Not to be used in known or suspected hypersensitivity to iodine or povidone or any other of the excipients listed in this leaflet.
- Not to be used in hyperfunction of the thyroid

hyperthyroidism), other manifest thyroid diseases esp. nodular colloidal goitre, endemic goitre, Hashimoto's thyroiditis, as well as before and after radioiodine therapy for hyperthyroidism, until a lasting cure has been obtained.

- It should not be used for 4 weeks prior to radioiodine scintigraphy or radioiodine treatment or thyroid carcinoma.
- Patients with goitre, thyroid nodules, or other thyroid diseases (especially elderly patients) are at risk of developing thyroid hyperfunction (hyperthyroidism) from the administration of large amounts of iodine.
- Not to be used on patients on concurrent lithium therapy.
- Not to be used in children under 6 years of age.

Precautions:

- Povidone-iodine should not cover for a long period large areas of the skin (e.g., not to more than 10% of the total body surface and for not longer than 14 days) unless strictly indicated. Even after the end of the treatment (up to 3 months) one should look for the early symptoms of possible hyperthyroidism and if necessary the thyroid function should be monitored.
- Special caution is needed when regular applications to broken skin are made to patients with pre-existing renal insufficiency.
- For mouthwash/gargle only. In instances of local irritation or sensitivity discontinue use.
- Keep out of the reach of children.

Interactions with other drugs and other forms of interactions:

- PVP-iodine complex is effective at pH values of between 2.0 and 7.0. It has to be expected that the complex will react with protein and other unsaturated organic compounds, leading to impairment of its effectiveness.
- The concomitant use of products containing enzymatic component, hydrogen peroxide, silver and tauro-lidine lead to a weakening effect of both substances.

- Simultaneous use with mercury products may lead to formation of a substance, which can damage the skin.
- Using this treatment may interfere with tests or thyroid function and can make a planned treatment of the thyroid with iodine impossible. After the end of the treatment an interval of at least 1-2 weeks should be allowed before a new scintigram is carried out.
- Contamination with Povidone-Iodine of several types of tests for the detection of occult blood in faeces or blood in urine may produce false-positive results.

Pregnancy and breast-feeding:

During pregnancy and lactation, BETADINE® Mouthwash/Gargle should only be used if strictly prescribed by the doctor (under medical prescription) and its use should be kept to the absolute minimum, as absorbed iodine can cross the placental barrier and can be secreted in breast milk. Povidone-Iodine use may induce transient hypothyroidism in the foetus or in the newborn. Povidone-Iodine should be avoided in such situations. In these cases a check of the child's thyroid function is necessary, especially in areas known for endemic low dietary iodine and tendency to goitre. Also, any possible ingestion of the Mouthwash/Gargle by the infant must be absolutely avoided.

4- How to use BETADINE® Mouthwash/Gargle?

- Route of administration: For local use only.
- 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, repeat up to four times a day if needed.
 - With existing lesions the mouth should be rinsed with the solution for two (2) minutes, up to four times a day, especially after meals.
 - The usual period of treatment (unless otherwise advised by your doctor) could last for about 14 days.
 - If there is no improvement of the symptoms after 2 to 5 days of regular use of the product, consult your doctor
 - Not to be used in children under 6 years of age.

Overdose

In the event of accidental or deliberate ingestion of BETADINE® Mouthwash/Gargle, contact immediately your doctor or your nearest hospital.

Symptoms: Abdominal symptoms, anuria, circulatory failure, edema of glottis resulting in asphyxia, or pulmonary edema and metabolic abnormalities.

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

5- Side effects

Rarely, hypersensitive skin reactions may occur (e.g. delayed contact-allergic reactions, which can appear in the form of itching, redness, small blisters or similar manifestations). Involvement of other organs has been reported in isolated cases.

In single cases acute, generalized, allergic reactions with drop in blood pressure and/or shortness of breath (anaphylactic reactions) have been reported. If you experience any of the above side effects or any other unusual effects, stop using the product and consult your doctor.

6- Storage Precautions:

- Store at or below 25°C.
- Do not use after the expiry date (see date printed on the packing)
- Keep out of the reach of children.
- Revised June 2014
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