

Product Licence Licence de mise en marché

Product Number/Numéro de produit: 00158291

Brand Name/Marque nominative: Betadine Mouthwash/Gargle

Issued to/Émise à:

Name of licensee/Nom du titulaire:

Purdue Pharma
575 Granite Court
Pickering, Ontario, L1W 3W8
Canada

Authorized for the following/Autorisé pour ce qui suit:

Dosage form/Forme posologique: Mouthwash/gargle

Recommended route of administration/Voie d'administration recommandée:

Buccal

Recommended dose/Dose recommandée:

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| Sub Population N/A : | For use as needed. As a routine mouthwash: use full strength or dilute to taste. Effective up to dilution of 1 part Betadine with 2 parts water. |
| Sub Population N/A : | For use as needed. As a gargle or mouthwash: use full strength for 30 seconds, hourly, or as directed by physician or dentist. |

Recommended duration of use/Durée d'utilisation recommandée:

N/A

Recommended use or purpose/Usage ou les fins recommandés:

As a mouthwash for routine use. Eliminates or reduces, offensive mouth odours. As a gargle or mouthwash as primary or adjunctive therapy in infections of the mouth and throat such as aphthous stomatitis, Vincent's infection, pharyngitis, oral moniliasis, tonsillitis and following oral surgery and dental procedures. Because of its effectiveness as a germicide, it may be used following oral surgery and dental procedures and to help relieve the pain and irritation of minor sore throat.

Risk Information/Renseignements sur les risques:

Cautions and Warnings

General: For external use only. Avoid contact with eyes. If contact occurs, flush eyes with water. In pre-operative preparation, avoid "pooling" beneath the patient. Prolonged exposure to wet solution may cause irritation or rarely, severe skin reactions. Chemical burns of skin due to "pooling" may occur (chemical burn of skin). Discontinue use and consult a physician promptly if skin irritation, contact dermatitis, hypersensitivity, or allergic reaction develops. These may be signs of a serious condition. Do not heat prior to application. Keep out of the reach of children. Patients with goiter, thyroid nodules, or other thyroid diseases (thyroid disorder) are at risk of developing thyroid hyperfunction (hyperthyroidism) from the administration of large amounts of iodine. In this patient population, povidone-iodine solution should not be applied for an extended period of time and to large areas of the skin unless strictly indicated. Even after the end of the treatment one should look for the early symptoms of possible hyperthyroidism and if necessary the thyroid function should be monitored. Newborns and small infants are at increased risk of developing hypothyroidism from the administration of large amounts of iodine. Because of the permeable nature of their skin and the increased sensitivity to iodine, the use of povidone-iodine should be kept to the absolute minimum in newborns and small infants. A check of the child's thyroid function (e.g. T4 levels and TSH levels) may be necessary. Any possible oral ingestion of povidone-iodine by the infant must be absolutely avoided. Betadine Mouthwash/Gargle: Consult your physician promptly for severe or persistent sore throat, or sore throat accompanied by high fever, headache, nausea or vomiting. Drug Interactions and Other Forms of Interactions: The 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 wound-treatment preparations containing enzymatic components leads to weakening of the effects of both substances. Products containing mercury, silver, hydrogen peroxide, alkali, tannic acid, and taurolidine may interact with povidone-iodine and should not be used concomitantly. Povidone-iodine products when used concomitantly or immediately after application of octenidine containing antiseptics in the same or adjacent sites may lead to transient dark discolorations in the areas involved. Note: Due to the oxidative effect of povidone-iodine solution various diagnostic agents can show false-positive lab results (e.g. tests with toluidine or gum guaiac for the determination of haemoglobin or glucose in the stool or the urine). Absorption of iodine from povidone-iodine solution may interfere with thyroid function tests. During the use of povidone-iodine solution the iodine uptake of the thyroid can be lowered; this can lead to interference with various investigations (thyroid scintigraphy, determination of PBI [protein-bound iodine], radioiodine diagnostics) and can make a planned treatment of the thyroid with iodine (radioiodine therapy) impossible. After the end of the treatment, an appropriate interval should be allowed before a new scintigram is carried out. Pregnancy and Lactation: During pregnancy and lactation,

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povidone-iodine solution should only be used if strictly indicated and its use should be kept to the absolute minimum. Because of the ability of iodine to pass through the placenta and be secreted in breast milk, and because of the increased sensitivity of the fetus and newborn to iodine, no large amounts of povidone-iodine should be administered during pregnancy and lactation. Moreover, iodine is concentrated in the breast milk, as compared with the serum. Povidone-iodine use may induce transient hypothyroidism with elevation of TSH (thyroid stimulating hormone) in the fetus or in the newborn. A check of the child's thyroid function may be necessary. Any possible oral ingestion of the solution by the infant must be absolutely avoided. In case of overdose: Call a Regional Poison Control Centre and/or your doctor and/or your local emergency number immediately, or go to your local hospital emergency, even if you do not notice any signs or symptoms. Overdose: Acute iodine toxicity is manifested by abdominal symptoms, anuria, circulatory collapse, pulmonary edema and metabolic abnormalities. Treatment is symptomatic and supportive.

Contra-Indications

Not to be used in known hypersensitivity to iodine or povidone. Not to be used in hyperfunction of the thyroid (hyperthyroidism), other manifest thyroid diseases as well as before and after radioactive iodine therapy. It should not be used prior to radioiodine scintigraphy (thyroid gland) or radioiodine treatment of thyroid carcinoma.

Known Adverse Reactions

Rarely, hypersensitive skin reactions may occur (e.g., delayed contact-allergic reactions (delayed type hypersensitivity reaction), which can appear in the form of pruritus, erythema, small blisters or similar manifestations). Very rarely, acute, generalized, allergic reactions (anaphylactic reactions) with drop in blood pressure (blood pressure decreased) and/or dyspnea as well as cases of acute skin and mucosal swelling (angioedema) have been reported. The long-term use of povidone-iodine solution for the treatment of wounds and burns over extensive areas of the skin can lead to a notable uptake of iodine. In isolated cases, patients with a history of thyroid disease can develop hyperfunction of the thyroid (iodine induced hyperthyroidism), sometimes with symptoms such as tachycardia or restlessness. Following uptake of large amounts of povidone-iodine (e.g., in the treatment of burns), the appearance of additional disorders of electrolyte imbalance and abnormal blood osmolarity, impairment of renal function with acute renal failure and metabolic acidosis have been described in the use of iodine-containing products.

Medicinal Ingredients/Ingrédients médicinaux:

Proper Name Nom propre	Common Name Nom usuel	Quantity per Dosage Unit Quantité par unité posologique	Extract Extrait	Potency Activité	Source Material Matière d'origine
Povidone-Iodine	Povidone-Iodine	1 %	N/A	N/A	Synthetic

This licence is issued by the Minister of Health under the authority of section 7 of the Natural Health Products Regulations. Sale of the described natural health product, including any changes thereto pursuant to section 11 of the Regulations, is subject to the Food and Drugs Act and to the Natural Health Products Regulations.

Cette licence est émise par la ministre de la Santé en vertu de l'article 7 du Règlement sur les produits de santé naturels. La vente du produit de santé naturel décrit dans la présente, y compris toute modification afférente au sens de l'article 11 du Règlement, est assujettie à la Loi sur les aliments et drogues et au Règlement sur les produits de santé naturels.

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Director General/Directrice générale
NHPD/DPSN