Product Licence

Product Number: 00158348

Brand Name: BETADINE® SOLUTION

Issued to:

Name of licensee:

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

Authorized for the following:

Dosage form: Solution

Recommended route of administration: Topical

Recommended dose:

Sub Population:	N/A

Recommended use or purpose:

Film-forming, non-staining and water-soluble. Dependable microbicide for situations such as:

- pre-operative skin preparation of the operative site
- disinfection of wounds, skin, genital and oropharyngeal mucosa
- anti-infective prophylaxis during hospital and office procedures (i.e., injections)

For topical use only. Use full strength for pre- and post-operative skin and mucus membrane antisepsis, prophylaxis and treatment of wounds, lacerations and burns, bacterial and mycotic infections of the skin, trichomonal, monilial and non-specific vaginitis, cervicitis, oral infections and dental procedures.

For Pre-operative Use: Clean the affected area. Following cleansing of the operative area, apply BETADINE SOLUTION at full strength as often as needed as a paint or wet soak. Allow to dry before applying surgical drapes.

Wounds, burns, skin lesions: Apply directly to affected area once or twice daily unless directed otherwise by a healthcare practitioner.

Recommended duration of use: N/A

Risk Information:

Cautions and Warnings

General: Avoid contact with eyes. If contact occurs, flush eyes with water. Do not heat prior to application. Keep out of the reach of children.

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.

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.

In instances of skin irritation, contact dermatitis or hypersensitivity, discontinue use. Do not heat prior to application.

Patients with goitre, thyroid nodules, or other non-acute thyroid diseases 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.

It should not be used prior to or after radioiodine scintigraphy or radioiodine treatment of thyroid carcinoma.

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 their increased sensitivity to iodine, the use of povidone-iodine should be kept to the absolute minimum in newborns and small infants. A check of their thyroid function (e.g., T_4 levels and TSH levels) may be necessary. Any oral ingestion of povidone-iodine by the infant must be avoided.

In oropharyngeal use, precautions should be taken to prevent aspiration of BETADINE SOLUTION into the respiratory tract, as this may cause complications such as pneumonitis. This may particularly occur in intubated patients.

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 a 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.

Due to the oxidative effect of povidone-iodine preparations various diagnostic agents can show false-positive lab results (e.g. tests with toluidine or gum guaiac for the determination of hemoglobin or glucose in the stool or the urine).

Absorption of iodine from povidone-iodine solution may lower the iodine uptake of the thyroid. 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.

Fertility, Pregnancy and Lactation: During pregnancy and lactation, 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 newborn's thyroid function may be necessary. Any oral ingestion of the solution by the infant must be avoided.

Overdose: Acute iodine toxicity is manifested by abdominal symptoms, anuria, circulatory collapse, pulmonary edema and metabolic abnormalities. Treatment is symptomatic and supportive.

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.

Contra-Indications

- Patients with known hypersensitivity to iodine or povidone
- Hyperthyroidism
- Other manifest thyroid disease (i.e., non-acute)
- Other acute thyroid diseases
- Before and after radioactive iodine therapy

Known Adverse Reactions

The adverse reactions are classified by body system according to their incidence (common or uncommon). Common adverse reactions have an incidence of ≥ 1% and adverse reactions effects have an incidence of < 1%.

Immune system disorders
Uncommon: Anaphylactic reaction and hypersensitivity

Endocrine disorders
Uncommon: Hyperthyroidism (sometimes with symptoms such as tachycardia or restlessness)* and hypothyroidism***

Metabolism and nutrition
Uncommon: Electrolyte imbalance** and metabolic acidosis**

Respiratory, thoracic and mediastinal disorders
Uncommon: Pneumonitis*****

Skin and subcutaneous disorders
Uncommon: Angioedema and contact dermatitis (with symptoms such as erythema, small blisters and pruritus)

Renal and urinary disorders
Uncommon: Acute renal failure** and blood osmolarity abnormal**

Injury poisoning and procedural complications
Uncommon: Chemical burn of skin****

* In patients with a history of thyroid disease (see Cautions and Warnings) following a notable uptake of iodine e.g., following long-term use of povidone-iodine solution for the treatment of wounds and burns over extensive areas of the skin.

** May occur following absorption of large amounts of povidone-iodine during the exposure of large skin or mucosal areas (e.g. in the treatment of burns)

*** Following prolonged or extensive use of povidone-iodine

**** May occur due to "pooling" beneath the patient in pre-operative preparation

***** Complication of aspiration, see Cautions and Warnings

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Medicinal Ingredients:

Proper Name	Common Name	Quantity per Dosage Unit	Extract	Potency	Source Material
Povidone-Iodine	Povidone-Iodine	10%	N/A	1.0%	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.

Issued: 2009-11-16	Revised/Amended: 2017-06-29

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Director General
NHPD