



Product Licence Licence de mise en marché

Product Number/Numéro de produit: 80087619

Brand Name/Marque nominative: Betadine First-Aid Solution

Other Brand Name(s)/Autre(s) marque(s) nominative(s):

Betadine Antiseptic Spray

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: Solution

Recommended route of administration/Voie d'administration recommandée:

Topical

Recommended dose/Dose recommandée:

Adults and Children : (Over 2 Years of Age): Apply 1 millilitre 1-3 times per day. Clean the affected area. Spray a small amount to wound 1 to 3 times daily. May be covered with a sterile bandage (allow to dry). Do not use on deep or puncture wounds, animal bites or serious burns.

Recommended duration of use/Durée d'utilisation recommandée:

For occasional use.

Recommended use or purpose/Usage ou les fins recommandés:

For cleansing of minor wounds such as cuts, scrapes and burns. Helps prevent and reduce the risk of infection by rapidly killing harmful bacteria, viruses and germs.

Risk Information/Renseignements sur les risques:

Cautions and Warnings

For external use only. Keep out of reach of children. If swallowed, call a Poison Control Center or a health care professional immediately. Avoid contact with eyes. If contact occurs, flush thoroughly with water. Do not apply over large areas of the body. If symptoms worsen or persist after seven days, or if irritation develops, discontinue use and consult a health care practitioner/professional. Consult a health care practitioner/professional before use on infants. Consult a health care practitioner/professional before use if you have a thyroid disease.

Contra-Indications

Do not use if you are pregnant or breastfeeding. Do not use if you are allergic to any of the ingredients.

Known Adverse Reactions

Rare anaphylactic reactions have been known to occur.

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
1-Vinyl-2-pyrrolidinone polymers, iodine complex	Povidone-iodine	5 %	N/A	N/A	Povidone-iodine (Synthetic)



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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.

Issued/émis le: 2018-08-07

Revised/Amended/Modifié le: 2019-03-24

**Director General/Directeur général
NHPD/DPSN**