



Product Licence Licence de mise en marché

Product Number/Numéro de produit: 80090099

Brand Name/Marque nominative: BETADINE COLD DEFENCE

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: Spray

Recommended route of administration/Voie d'administration recommandée:

Nasal

Recommended dose/Dose recommandée:

Children : (1-4 years): Spray one dose 1-3 time(s) per day into each nostril. Consult a healthcare practitioner prior to use.

Additional Dosage Information: 1 spray = 0.14 mL solution

Adults and Children : (over 4): Spray one dose 1-3 time(s) per day into each nostril.
Additional Dosage Information: 1 spray = 0.14 mL solution

Recommended duration of use/Durée d'utilisation recommandée:

N/A

Recommended use or purpose/Usage ou les fins recommandés:

Helps moisten the nasal lining to protect it from dryness.
Helps keep nasal tissue moist preventing dryness and crusting.
Soothes and moisturizes nasal passages.
Hydrates inside of nose. Soothing formula.
Forms a moisturising protective film on the nasal lining.
Relieves symptoms of upper respiratory tract infections.
Relieves congestion and runny nose caused by colds.
Relieves congestion and runny nose.
Provides relief of congestion and runny nose caused by upper respiratory tract infections.
Helps in the early treatment of the common cold.
Helps treat the common cold.
Creates a protective layer in the nasal cavity that helps to reduce the spread of cold viruses.
Creates a barrier against viruses to reduce the spread of colds.
Forms a barrier to block viruses.
Traps cold viruses.
Helps trap and disable viruses in the nasal cavity.
Helps treat viral infections when used at the first sign of a cold.
Helps treat colds at the first sign.
Clinically proven to shorten the duration of a cold when used at the first sign.
Clinically proven to defend against colds.
Helps to reduce the length of a cold when used at the onset of symptoms.
Helps prevent viruses from spreading and multiplying.
Relieves cold symptoms by reducing the number of viruses.

Risk Information/Renseignements sur les risques:

Cautions and Warnings

If symptoms persist or worsen, consult a healthcare practitioner.

One spray bottle should be used by the same person only to avoid contamination (spreading germs).

If nasal burning, nasal irritation or nausea occurs, discontinue use.

Keep out of reach of children.

Contra-Indications

Do not use if you have a known hypersensitivity to carrageenan.

Known Adverse Reactions

None.



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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
Sodium chloride	Sodium chloride	.5 %	N/A	N/A	Sodium chloride
iota-Carrageenan	iota-Carrageenan	1.2 mg	N/A	N/A	EC 3.1.1

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: 2019-01-11

Revised/Amended/Modifié le: N/A

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