Public Summary

Summary for ARTG Entry:	349939 Saline Ultra Nasal Spray
ARTG entry for	Medicine Listed
Sponsor	Brauer Natural Medicine Pty Ltd
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia
ARTG Start Date	27/11/2020
Product Category	Medicine
Status	Active
Approval Area	Listed Medicines

Conditions

The sponsor shall keep records relating to this listed medicine as are necessary to: (a) Expedite recall if necessary of any batch of the listed medicine, (b) Identify the manufacturer(s) of each batch of the listed medicine. Where any part of or step in manufacture in Australia of the listed medicine is sub-contracted to a third party who is not the sponsor, copies of relevant Good Manufacturing Practice agreements relation to such manufacture shall be kept.

The sponsor shall retain records of the distribution of the listed medicine for a period of five years and shall provide the records or copies of the records to the Complementary Medicines Branch, Therapeutic Goods Administration, upon request.

Where a listed medicine is distributed overseas as well as in Australia, product recall or any other regulatory action taken in relation to the medicine outside Australia which has or may have relevance to the quality, safety or efficacy of the goods distributed in Australia, must be notified to the National Manager Therapeutic Goods Administration, immediately the action or information is known to the sponsor.

Products

1 . Saline Ultra Nasal Spray

Product Type Single Medicine Product **Effective Date** 27/11/2020

Permitted Indications

Decongestant/relieve nasal congestion

Unblock/clear nasal passages

Traditionally used in Aromatherapy to decrease/reduce/relieve symptoms of common cold

Traditionally used in Aromatherapy to decrease/reduce/relieve cough

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Spray, nasal

Route of Administration Nasal

Visual Identification

Active Ingredients

Eucalyptus Oil **1.5 mg/mL**

Peppermint Oil	**1.5 mg/mL**
sodium chloride	**9 mg/mL**
Other Ingredients (Excipients)	
benzalkonium chloride	
dibasic sodium phosphate dihydrate	
disodium edetate	
monobasic sodium phosphate dihydrate	
purified water	

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