



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	348159	Saline Nasal Spray for Kids
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	12/11/2020	
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 Nasal Spray for Kids

Product Type	Single Medicine Product	Effective Date	12/11/2020
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Permitted Indications

Decongestant/relieve nasal congestion in children

Traditionally used in Homoeopathic medicine to decongestant/relieve nasal congestion in children

Traditionally used in Homoeopathic medicine to unblock/clear nasal passages in children

Unblock/clear nasal passages in children

Traditionally used in Homoeopathic medicine to decrease/reduce excess mucous in children

Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild upper respiratory tract congestion in children

Indication Requirements

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

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

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

Respiratory tract infections must be qualified by 'mild'.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains homoeopathic ingredients.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Spray, nasal

Route of Administration Nasal

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Visual Identification

Active Ingredients

Allium cepa bulb (Homeopathic)	200 microlitre/mL
Anemone pulsatilla whole plant (Homeopathic)	200 microlitre/mL
calcium sulfide (Homeopathic)	200 microlitre/mL
potassium dichromate (Homeopathic)	200 microlitre/mL
potassium iodide (Homeopathic)	200 microlitre/mL
sodium chloride	9 mg/mL

Other Ingredients (Excipients)

benzalkonium chloride
dibasic sodium phosphate dihydrate
disodium edetate
monobasic sodium phosphate dihydrate

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