



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	351127	Allergy Oral Spray
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Brauer Natural Medicine Pty Ltd	
<b>Postal Address</b>	PO Box 234, TANUNDA, SA, 5352 Australia	
<b>ARTG Start Date</b>	8/12/2020	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

Colouring agents used in listed medicine for ingestion, other than those listed for export only under section 25 of the Act, shall be only those included in the list of 'Colourings permitted in medicines for oral use'.

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 . Allergy Oral Spray

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	29/07/2022
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#### Permitted Indications

- Traditionally used in Homoeopathic medicine to relieve itchy eyes
- Traditionally used in Homoeopathic medicine to relieve eye redness
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve watery eyes/excessive lacrimation
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve diarrhoea
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve colic (wind/gas pain)
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve excess intestinal gas
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve flatulence/carminative
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve abdominal cramping
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve abdominal feeling of fullness
- Traditionally used in Homoeopathic medicine to relieve excessive belching
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Homoeopathic medicine to helps decrease/reduce/relieve symptoms of food intolerance
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of hayfever
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of skin hives
- Traditionally used in Homoeopathic medicine to helps decrease/reduce/relieve symptoms of mild allergies
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of allergic rhinitis
- Traditionally used in Homoeopathic medicine to helps decrease/reduce/relieve symptoms of seasonal allergies
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve headache symptoms
- Traditionally used in Homoeopathic medicine to decongestant/relieve nasal congestion
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve bronchial mucous congestion
- Traditionally used in Homoeopathic medicine to decrease/reduce excess chest phlegm
- Traditionally used in Homoeopathic medicine to decrease/reduce excess mucous
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild upper respiratory tract congestion
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve sneezing
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild bronchial cough
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve cough

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Traditionally used in Homoeopathic medicine to relieve dry unproductive cough  
Traditionally used in Homoeopathic medicine to helps decrease/reduce/relieve nasal itching  
Traditionally used in Homoeopathic medicine to relieve runny/dripping nose  
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Traditionally used in Homoeopathic medicine to antipruritic/Relieves itchy skin  
Traditionally used in Homoeopathic medicine to relieve red skin rash

#### Indication Requirements

Label statement: If symptoms persist, talk to your health professional.  
Product presentation must not imply or refer to gastro oesophageal reflux disease.  
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.  
Product presentation must not imply or refer to serious allergic conditions such as anaphylaxis.  
Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).  
Respiratory tract infections must be qualified by 'mild'.  
Product presentation must only refer to mild bronchitis.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications



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 Therapeutic Goods Administration

No Specific Indications included on Record

**Warnings**

Homoeopathic product/preparation or medicine (or words to that effect)

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form** Spray, solution

**Route of Administration** Sublingual

**Visual Identification**

**Active Ingredients**

<b>Anemone pulsatilla whole plant (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
Equivalent: Anemone pulsatilla	.0091 picogram/mL
<b>antimony potassium tartrate trihydrate (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
<b>Bryonia alba root (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
Equivalent: Bryonia alba	.0091 picogram/mL
<b>histamine dihydrochloride (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
<b>Matricaria chamomilla whole plant (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
Equivalent: Matricaria chamomilla	.0091 picogram/mL
<b>Oyster shell (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
<b>silver nitrate (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
<b>sodium chloride (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
<b>Strychnos nux-vomica seed (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
Equivalent: Strychnos nux-vomica	.0091 picogram/mL
Equivalent: strychnine (of Strychnos spp.)	.0002 picogram/mL
<b>Toxicodendron pubescens twig leafy young (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
Equivalent: Toxicodendron pubescens	.0091 picogram/mL
<b>Urtica urens whole plant (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
Equivalent: Urtica urens	.0091 picogram/mL

**2 . Allergy Oral Spray**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	29/07/2022
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**Standard Indications**

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**Specific Indications**

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**Warnings**

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**Additional Product information**

**Pack Size/Poison information**

Pack Size	Poison Schedule
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**Components**

**1 . Formulation 1**

**Dosage Form**                      Spray, solution  
**Route of Administration**      Sublingual

**Visual Identification**

**Active Ingredients**

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