



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	351124	Snoreeze 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 . Snoreeze Oral Spray**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	8/12/2020
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**Permitted Indications**

- Traditionally used in Homoeopathic medicine to enhance/promote/increase refreshing sleep
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve sleeplessness
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve disturbed/restless sleep
- Traditionally used in Homoeopathic medicine to decongestant/relieve nasal congestion
- Traditionally used in Homoeopathic medicine to unblock/clear nasal passages
- 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 helps enhance/improve nose breathing
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve snoring

**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**

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	9.1 ng/mL
<b>canine milk (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
<b>histamine dihydrochloride (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
<b>honey bee (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
<b>Krameria lappacea root (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
<b>Lemna minor whole plant (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
Equivalent: Lemna minor	9.1 ng/mL
<b>potassium dichromate (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
<b>Rheum officinale root and rhizome (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
Equivalent: Rheum officinale	9.1 microgram/mL
Equivalent: Hydroxyanthracene derivatives calculated as rhein	.0018 microgram/mL
<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.)	0 microgram/mL
<b>Teucrium marum whole plant (Homeopathic)</b>	<b>90.909 microlitre/mL</b>
Equivalent: Teucrium marum	9.1 ng/mL
<b>zinc (Homeopathic)</b>	<b>90.909 microlitre/mL</b>

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