



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	351124	Snoreeze Oral Spray
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	8/12/2020	
Product Category	Medicine	
Status	Active	
Approval Area	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

Product Type	Single Medicine Product	Effective Date	29/07/2022
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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
- Traditionally used in Homoeopathic medicine to enhance/promote/increase refreshing sleep
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve sleeplessness
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- 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.
- 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'.

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



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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

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Spray, solution

Route of Administration Sublingual

Visual Identification

Active Ingredients

Anemone pulsatilla whole plant (Homeopathic)	90.909 microlitre/mL
Equivalent: Anemone pulsatilla	9.1 ng/mL
canine milk (Homeopathic)	90.909 microlitre/mL
histamine dihydrochloride (Homeopathic)	90.909 microlitre/mL
honey bee (Homeopathic)	90.909 microlitre/mL
Krameria lappacea root (Homeopathic)	90.909 microlitre/mL
Lemna minor whole plant (Homeopathic)	90.909 microlitre/mL
Equivalent: Lemna minor	9.1 ng/mL
potassium dichromate (Homeopathic)	90.909 microlitre/mL
Rheum officinale root and rhizome (Homeopathic)	90.909 microlitre/mL
Equivalent: Rheum officinale	9.1 microgram/mL
Equivalent: Hydroxyanthracene derivatives calculated as their	.0018 microgram/mL
Strychnos nux-vomica seed (Homeopathic)	90.909 microlitre/mL
Equivalent: Strychnos nux-vomica	.0091 picogram/mL
Equivalent: strychnine (of Strychnos spp.)	0 microgram/mL
Teucrium marum whole plant (Homeopathic)	90.909 microlitre/mL
Equivalent: Teucrium marum	9.1 ng/mL
zinc (Homeopathic)	90.909 microlitre/mL

2 . Snoreeze Oral Spray

Product Type	Single Medicine Product	Effective Date	29/07/2022
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Specific Indications

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Warnings

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Pack Size/Poison information

Pack Size	Poison Schedule
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