



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	351128	Hayfever 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 . Hayfever Oral Spray

Product Type	Single Medicine Product	Effective Date	8/12/2020
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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 symptoms of hayfever
- 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 decongestant/relieve nasal congestion
- 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 relieve runny/dripping nose

Indication Requirements

- Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).
- 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.
- Product presentation must not imply or refer to serious allergic conditions such as anaphylaxis.
- 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



Australian Government
Department of Health
Therapeutic Goods Administration

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Spray, solution

Route of Administration Sublingual

Visual Identification

Active Ingredients

Allium cepa bulb (Homeopathic)	100 microlitre/mL
Equivalent: Allium cepa	1 microgram/mL
Ambrosia artemisiifolia whole plant (Homeopathic)	100 microlitre/mL
Equivalent: Ambrosia artemisiifolia	1 picogram/mL
arsenic triiodide (Homeopathic)	100 microlitre/mL
arsenic trioxide (Homeopathic)	100 microlitre/mL
Brassica nigra seed (Homeopathic)	100 microlitre/mL
Equivalent: Brassica nigra	.01 picogram/mL
Equivalent: allyl isothiocyanate	.0001 picogram/mL
Euphrasia officinalis whole plant (Homeopathic)	100 microlitre/mL
Equivalent: Euphrasia officinalis	1 microgram/mL
Lobaria pulmonaria whole plant (Homeopathic)	100 microlitre/mL
Equivalent: Lobaria pulmonaria	1 microgram/mL
naphthalene (Homeopathic)	100 microlitre/mL
potassium iodide (Homeopathic)	100 microlitre/mL
Equivalent: iodine	7.6 picogram/mL
Schoenocaulon officinale seed (Homeopathic)	100 microlitre/mL
Equivalent: Schoenocaulon officinale	1 microgram/mL

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