



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	124132	BRAUER DRY COUGH
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	10/12/2005	
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 . BRAUER DRY COUGH

Product Type	Single Medicine Product	Effective Date	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 antipyretic/febrifuge/relieve mild fever/reduce body temperature/body cooling
- 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 decongestant/relieve nasal congestion
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve mild bronchial irritation
- 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 expectorant/clear respiratory tract mucous
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve chills associated with common cold
- Traditionally used in Homoeopathic medicine to relieve symptoms of mild upper respiratory tract infections
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of common cold
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve cough
- Traditionally used in Homoeopathic medicine to relieve dry unproductive cough
- Traditionally used in Homoeopathic medicine to relieve dry throat
- Traditionally used in Homoeopathic medicine to relieve hoarseness of voice
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve throat irritation
- Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of laryngitis
- Traditionally used in Homoeopathic medicine to relieve loss of voice
- Traditionally used in Homoeopathic medicine to relieve symptoms of sore throat/pharyngitis

Indication Requirements



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Product presentation must only refer to mild bronchitis.

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

Label statement: Not to be used in children under 5 years.

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

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

Contains hydroxybenzoates (or words to this effect) if the medicines contains more than one hydroxybenzoate source OR Contains (insert the approved name of hydroxybenzoate used)(or words to this effect) if product contains one hydroxybenzoate source.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

Aconitum napellus whole plant (Homeopathic)	1 microlitre/mL
Equivalent: Total alkaloids (of Aconitum spp.)	.75 picogram/mL
Atropa belladonna whole plant (Homeopathic)	1 microlitre/mL
Equivalent: Alkaloids calculated as hyoscyamine	0 picogram/mL
Equivalent: atropine	0 picogram/mL
Bryonia alba root (Homeopathic)	1 microlitre/mL
Hyoscyamus niger whole plant (Homeopathic)	1 microlitre/mL
Equivalent: Hyoscyamine	.016 picogram/mL
Equivalent: Alkaloids calculated as hyoscyamine	.04 picogram/mL
marine sponge (Homeopathic)	1 microlitre/mL
phosphorus (Homeopathic)	1 microlitre/mL
potassium dichromate (Homeopathic)	1 microlitre/mL
Rumex crispus root (Homeopathic)	1 microlitre/mL
Sanguinaria canadensis rhizome (Homeopathic)	1 microlitre/mL

Other Ingredients (Excipients)

ethanol absolute

Flavour

glycerol

methyl hydroxybenzoate

propyl hydroxybenzoate

purified water

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