



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

## Public Summary

<b>Summary for ARTG Entry:</b>	281768	Brauer Baby Saline Nasal Drops
<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>	26/10/2016	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 Baby Saline Nasal Drops

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	26/10/2016
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#### Permitted Indications

No Permitted Indications included on Record

#### Indication Requirements

No Indication Requirements included on Record

#### Standard Indications

Aids, assists or helps in the maintenance of general well-being

#### Specific Indications

Sodium chloride (saline) solution may assist in relieving nasal congestion.  
Contains Allium cepa which is traditionally used in homeopathic medicine for the relief of catarrhal conditions and nasal discharge.  
Contains Allium cepa which is traditionally used in homeopathic medicine for the relief of mild hayfever and sneezing.  
Contains Calcium sulfide (Hepar sulfuris) which is traditionally used in homeopathic medicine for the relief of catarrhal conditions and nasal discharge.  
Contains Calcium sulfide (Hepar sulfuris) which is traditionally used in homeopathic medicine to assist with the symptoms of mild hay fever.  
Contains Potassium dichromate (Kali bichromicum) which is traditionally used in homeopathic medicine for the relief of nasal catarrh and mucus.  
Contains Potassium dichromate (Kali bichromicum) which is traditionally used in homeopathic medicine for the relief of nasal snuffles in children.  
Contains Potassium dichromate (Kali bichromicum) which is traditionally used in homeopathic medicine for the relief of minor inflammation of the frontal sinus.  
Contains Potassium iodide (Kali iodatum) which is traditionally used in homeopathic medicine for the relief of sinus pain and nasal catarrh.  
Contains Potassium iodide (Kali iodatum) which is traditionally used in homeopathic medicine for the relief of nasal congestion and blocked sinus.  
Contains Anemone pulsatilla (Pulsatilla) which is traditionally used in homeopathic medicine to relieve thick yellow-green nasal mucus and nasal congestion.  
Contains Anemone pulsatilla (Pulsatilla) which is traditionally used in homeopathic medicine for the relief of mild sinusitis.  
Brauer Baby Saline Nasal Drops is a saline solution that contains ingredients traditionally used in homeopathic medicine for the relief of nasal congestion, mild hayfever, sneezing and symptoms of sinusitis.

#### Warnings

Contains homeopathic ingredients.

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If symptoms persist consult your healthcare practitioner (or words to that effect).

**Additional Product information**

**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Nasal Drops, solution

**Route of Administration** Nasal

**Visual Identification**

**Active Ingredients**

Allium cepa (Homeopathic)	200 microlitre/mL
Anemone pulsatilla (Homeopathic)	200 microlitre/mL
calcium sulfide (Homeopathic)	200 microlitre/mL
potassium dichromate (Homeopathic)	200 microlitre/mL
potassium iodide (Homeopathic)	200 microlitre/mL
sodium chloride	8 mg/mL

**Other Ingredients (Excipients)**

benzalkonium chloride

dibasic sodium phosphate dihydrate

disodium edetate

monobasic sodium phosphate dihydrate

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