Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	281588 Brauer Baby Saline Nasal Spray
ARTG entry for	Medicine Listed
Sponsor	Brauer Natural Medicine Pty Ltd
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia
ARTG Start Date	21/10/2016
Product Category	Medicine
Status	Active
Approval Area	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 Spray

Product Type Single Medicine Product **Effective Date** 13/12/2019

Permitted Indications

Unblock/clear nasal passages in healthy infants

Unblock/clear nasal passages in children

Traditionally used in Homoeopathic medicine to unblock/clear nasal passages

Traditionally used in Homoeopathic medicine to unblock/clear nasal passages in children

Traditionally used in Homoeopathic medicine to unblock/clear nasal passages in healthy infants

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains homoeopathic ingredients.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Spray, nasal
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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