



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	347981	Baby & Child Teething Gel
ARTG entry for	Medicine Listed	
Sponsor	Brauer Natural Medicine Pty Ltd	
Postal Address	PO Box 234, TANUNDA, SA, 5352 Australia	
ARTG Start Date	11/11/2020	
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.

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 . Baby & Child Teething Gel

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

Traditionally used in Homoeopathic medicine to relieve feelings of general malaise/general debility
Traditionally used in Homoeopathic medicine to relieve weariness/tiredness/fatigue/feeling of weakness
Traditionally used in Homoeopathic medicine to relieve itchy eyes
Traditionally used in Homoeopathic medicine to relieve eye redness
Traditionally used in Homoeopathic medicine to relieve eye soreness
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve watery eyes/excessive lacrimation
Traditionally used in Homoeopathic medicine to decrease/reduce/relieves bleeding gums
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve gum soreness/pain/discomfort
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve cracks in the corner of the mouth
Traditionally used in Homoeopathic medicine to relieve dry mouth
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve toothache
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve teething/tooth pain in healthy children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve teething/tooth pain in healthy infants over 6 months of age
Traditionally used in Homoeopathic medicine to antiemetic/Decrease/reduce/relieve vomiting
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve nausea
Traditionally used in Homoeopathic medicine to relieve irritability in children
Traditionally used in Homoeopathic medicine to relieve irritability
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve restlessness/excess nervous energy in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve restlessness/excess nervous energy
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of stress
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve nervous tension/unrest
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve symptoms of mild anxiety
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve sleeplessness
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve disturbed/restless sleep in healthy infants over 6 months of age
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve disturbed/restless sleep in children
Traditionally used in Homoeopathic medicine to decrease/reduce/relieve disturbed/restless sleep

Indication Requirements

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

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Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must only refer to mild anxiety.

Product presentation must not imply or refer to recurrent or persistent mouth lesions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

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

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Gel
Route of Administration Oral Application

Visual Identification

Active Ingredients

Aconitum napellus whole plant (Homeopathic)	10 microlitre/g
Equivalent: Total alkaloids (of Aconitum spp.)	0 picogram/g
Actaea spicata rhizome (Homeopathic)	10 microlitre/g
Equivalent: Actaea spicata	1 microgram
Atropa belladonna whole plant (Homeopathic)	10 microlitre/g
Equivalent: Alkaloids calculated as hyoscyamine	0 picogram/g
Equivalent: atropine	0 picogram/g
Citrullus colocynthis fruit flesh (Homeopathic)	10 microlitre/g
colloidal anhydrous silica (Homeopathic)	10 microlitre/g
creosote (Homeopathic)	10 microlitre/g
hahnemann's soluble mercury (Homeopathic)	10 microlitre/g
Matricaria chamomilla whole plant (Homeopathic)	10 microlitre/g
Strychnos nux-vomica seed (Homeopathic)	10 microlitre/g
Equivalent: strychnine (of Strychnos spp.)	0 picogram/g

Other Ingredients (Excipients)

citric acid
dibasic sodium phosphate dihydrate
Flavour
glycerol
hyetellose
potassium sorbate
purified water

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