



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	312628	Baby Gripe Water
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Evolution Health Pty Ltd	
<b>Postal Address</b>	74-86 Garden Road, Clayton, VIC, 3168 Australia	
<b>ARTG Start Date</b>	17/12/2018	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Baby Gripe Water

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	27/09/2023
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#### Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve colic (wind/gas pain)

Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal griping pain

#### 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 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.

If symptoms persist, seek the advice of a healthcare professional.

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.

#### Additional Product information

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
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#### Components

##### 1 . Formulation 1

**Dosage Form** Oral Liquid

**Route of Administration** Oral

#### Visual Identification



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**Active Ingredients**

Caraway Oil	60 microgram/mL
Cardamom Oil	18 microgram/mL
Cinnamon Bark Oil	60 microgram/mL
Clove Bud Oil	60 microgram/mL
Dill Seed Oil	900 microgram/mL

**Other Ingredients (Excipients)**

methyl hydroxybenzoate  
purified water  
sodium metabisulfite  
sucrose

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Public Summary