



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

## Public Summary

<b>Summary for ARTG Entry:</b>	321101	Chewable Ginger
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Factors Group Australia Pty Ltd	
<b>Postal Address</b>	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
<b>ARTG Start Date</b>	31/07/2019	
<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.

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 . Chewable Ginger

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	31/07/2019
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### Permitted Indications

- Decrease/reduce/relieve mild rheumatic aches and pains
- Helps enhance/improve/promote blood circulation to the peripheral areas of the body (legs, hands and feet)
- Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- Maintain/support healthy digestive system function
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to decrease/reduce/relieve digestive spasms
- Decrease/reduce food stagnation associated with poor or sluggish digestion
- Antiemetic/Decrease/reduce/relieve vomiting
- Traditionally used in Western herbal medicine to decrease/reduce/relieve nausea
- Helps reduce occurrence of symptoms of motion/travel/sea sickness
- Decrease/reduce/relieve mild dizziness/vertigo
- Relieves mid-cycle menstrual pain
- Decrease/reduce/relieve menstrual spasms/cramps
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of common colds and flu
- Traditionally used in Western herbal medicine to expectorant/clear respiratory tract mucous
- Traditionally used in Western herbal medicine to antitussive/cough suppressant
- Traditionally used in Western herbal medicine to decrease/reduce/relieve cough

### Indication Requirements



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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 only refer to mild vertigo.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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

Product presentation must only refer to mild rheumatic aches/pains.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.  
 Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Product presentation must not imply or refer to eating disorders.

Product presentation must not imply or refer to serious cardiovascular conditions.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea [or words to that effect].

**Additional Product information**

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

**Pack Size/Poison information**

Pack Size	Poison Schedule

**Components**

**1 . Formulation 1**

<b>Dosage Form</b>	Tablet, chewable
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

<b>Zingiber officinale root Extract dry concentrate</b>	<b>20 mg</b>
Equivalent: Zingiber officinale (Dry)	500 mg

**Other Ingredients (Excipients)**

- hypolose
- magnesium stearate
- microcrystalline cellulose
- stearic acid
- Stevia rebaudiana
- xylitol

Public Summary

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