



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	321101	Chewable Ginger
ARTG entry for	Medicine Listed	
Sponsor	Factors Group Australia Pty Ltd	
Postal Address	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
ARTG Start Date	31/07/2019	
Product Category	Medicine	
Status	Active	
Approval Area	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

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

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

Product presentation must not imply or refer to eating disorders.

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

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.

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

Product presentation must only refer to mild vertigo.

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

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

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
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Components

1 . Formulation 1

Dosage Form	Tablet, chewable
Route of Administration	Oral

Visual Identification

Active Ingredients

Zingiber officinale root Extract dry concentrate	20 mg
Equivalent: Zingiber officinale (Dry)	500 mg

Other Ingredients (Excipients)

hypromellose
magnesium stearate
microcrystalline cellulose
stearic acid
Stevia rebaudiana
xylitol

Public Summary

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