



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	359997	Henry Blooms Ginger Calm 1000
ARTG entry for	Medicine Listed	
Sponsor	Phytologic Holdings Pty Limited	
Postal Address	16-20 Baker Street, Banksmeadow, NSW, 2019 Australia	
ARTG Start Date	7/04/2021	
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.

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 . Henry Blooms Ginger Calm 1000

Product Type	Single Medicine Product	Effective Date	13/05/2021
---------------------	-------------------------	-----------------------	------------

Permitted Indications

Maintain/support general health and wellbeing
Traditionally used in Chinese medicine to anti-inflammatory/relieve inflammation
Maintain/support healthy digestive system function
Maintain/support healthy digestion
Decrease/reduce/relieve symptoms of indigestion/dyspepsia
Relieve digestive discomfort
Decrease/reduce/relieve nausea
Helps reduce occurrence of symptoms of motion/travel/sea sickness
Decrease/reduce/relieve symptoms of motion/travel/sea sickness
Decrease/reduce/relieve morning sickness

Indication Requirements

Label statement: If symptoms persist, talk to your health professional.
Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
Product presentation must not imply or refer to severe morning sickness such as hyperemesis gravidarum
Label statement: If symptoms persist or worsen talk to your medical practitioner.
Product presentation must not imply or refer to gastro oesophageal reflux disease.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Zingiber officinale root Extract dry concentrate	40 mg
Equivalent: Zingiber officinale (Dry)	1000 mg

Other Ingredients (Excipients)

hypromellose

magnesium stearate

maltodextrin

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary