

Australian Government

Department of Health and Aged Care

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 6/12/2022

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

Indication Requirements

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

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

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

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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

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