

Australian Government

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 356118 BLOOMS GREEN LIPPED MUSSEL AND TURMERIC

ARTG entry for Medicine Listed

Sponsor Phytologic Holdings Pty Limited

Postal Address 16-20 Baker Street, Banksmeadow, NSW, 2019

Australia

ARTG Start Date 3/03/2021
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. BLOOMS GREEN LIPPED MUSSEL AND TURMERIC

Product Type Single Medicine Product Effective Date 14/07/2022

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Helps reduce/decrease free radical damage to body cells

Maintain/support general health and wellbeing

Anti-inflammatory/relieve inflammation

Decrease/reduce/relieve mild joint aches and pains

Decrease/reduce/relieve symptoms of mild arthritis/mild osteoarthritis

Helps maintain/supports healthy joint cartilage growth/development/production

Maintain/support joint health

Decrease/reduce/relieve mild joint inflammation/swelling

Maintain/support joint mobility/flexibility

Decrease/reduce/relieve mild joint pain/soreness

Decrease/reduce/relieve mild joint stiffness

Relieve digestive discomfort

Indication Requirements

Product presentation must only refer to mild joint symptoms.

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.

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

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 any form of arthritis or osteoarthritis unless qualified as mild.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Page 1 of 2



Australian Government

Department of Health

Therapeutic Goods Administration

Warnings

Derived from seafood.

'Contains mollusc' or 'Contains mollusc products'.

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

 Curcuma longa rhizome Extract dry concentrate
 75 mg

 Equivalent: Curcuma longa (Dry)
 1.5 g

 Green lipped mussel dried
 500 mg

 Piper nigrum fruit Extract dry concentrate standardised
 5.26 mg

 Equivalent: Piper nigrum (Dry)
 131.5 mg

Other Ingredients (Excipients)

hypromellose

magnesium stearate

maltodextrin

purified water

silicon dioxide

sorbitol

[©] 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.