



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	374416	Vital Calcium
ARTG entry for	Medicine Listed	
Sponsor	Martin & Pleasance Pty Ltd	
Postal Address	PO Box 2007, SOUTH MELBOURNE, VIC, 3205 Australia	
ARTG Start Date	9/09/2021	
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 . Vital Calcium

Product Type	Single Medicine Product	Effective Date	9/09/2021
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Permitted Indications

Helps enhance/promote general health and wellbeing

Maintain/support general health and wellbeing

A diet deficient in calcium can lead to osteoporosis in later life. Calcium may help prevent osteoporosis when dietary intake is inadequate

Helps enhance/promote healthy muscle function

Maintain/support muscle function

Enhance/improve/promote/increase (state vitamin/mineral/nutrient) levels in the body

Maintain/support (state vitamin/mineral/nutrient) levels in the body

Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Maintain/support (state vitamin/mineral) within normal range

Indication Requirements

Indication can only be used for medicines that contain calcium as an active ingredient and the recommended daily dose of the medicine must provide at least 290 milligrams of elemental calcium.

Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

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



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Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Brassica juncea leaf Powder	12.5 mg
Brassica oleracea var. gemmifera leaf Powder	12.5 mg
Brassica rapa leaf Powder	12.5 mg
calcified lithothamnion tophiforme	475 mg

Other Ingredients (Excipients)

carrageenan

colloidal anhydrous silica

hypromellose

magnesium stearate

maize starch

microcrystalline cellulose

potassium acetate

purified water

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