



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	282024	BioActivated Calcium
ARTG entry for	Medicine Listed	
Sponsor	Biomedica Nutraceuticals Pty Ltd	
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	2/11/2016	
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 . BioActivated Calcium

Product Type	Single Medicine Product	Effective Date	23/09/2019
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Permitted Indications

- Maintain/support collagen formation
- Maintain/support general health and wellbeing
- Maintain/support healthy teeth
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support bone strength
- Help maintain/support bone mineralisation
- A diet deficient in calcium can lead to osteoporosis in later life. Calcium may help prevent osteoporosis when dietary intake is inadequate
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Helps maintain/support joint cartilage health
- Antispasmodic/spasmolytic
- Maintain/support healthy muscle contraction function
- Maintain/support muscle health
- Maintain/support muscle function
- 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.

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.

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: [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).

Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Indication only for use for medicines that contain vitamin D as an active ingredient. The medicines may only contain a maximum recommended daily dose of 25 micrograms or less of vitamin D and as a minimum, also contain at least 25% of the RDI in the recommended daily dose of vitamin D.

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

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
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Components

1 . Formulation 1

Dosage Form Powder
Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	9.58 mg/g
borax	2.205 mg/g
Equivalent: boron	250 microgram/g
calcium citrate	197.47 mg/g
Equivalent: calcium	41.67 mg/g
calcium phosphate	157.66 mg/g
Equivalent: phosphorus	31.48 mg/g
Equivalent: calcium	58.3 mg/g
colecalfiferol	.0016 mg/g
colloidal anhydrous silica	7.13 mg/g
Equivalent: silicon	3.33 mg/g
hydroxyapatite	33.333 mg/g
Equivalent: phosphorus	4.2 mg/g
Equivalent: calcium	8.33 mg/g
lysine hydrochloride	41.65 mg/g
Equivalent: lysine	33.34 mg/g
magnesium citrate	36.1 mg/g
Equivalent: magnesium	5.83 mg/g
magnesium phosphate tribasic	165 mg/g
Equivalent: magnesium	34.17 mg/g
manganese amino acid chelate	4.17 mg/g
Equivalent: manganese	417 microgram/g
phytomenadione	6.7 microgram/g
zinc citrate dihydrate	3.11 mg/g

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Equivalent: zinc

1 mg/g

Other Ingredients (Excipients)

Acacia

dl-alpha-tocopherol

Flavour

glycine

Guar Gum

maize starch

medium chain triglycerides

rice starch

silicon dioxide

sucrose

thaumatin

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Public Summary