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.

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** 18/11/2022

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

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.

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

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).

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

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: calcium	58.3 mg/g
colecalciferol	**.0016 mg/g**
colloidal anhydrous silica	**7.13 mg/g**
Equivalent: silicon	3.33 mg/g
hydroxyapatite	**33.333 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**
Equivalent: zinc	1 mg/g

Other Ingredients (Excipients)

Acacia
dl-alpha-tocopherol
Flavour
glycine
Guar Gum
maize starch
maltodextrin

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medium chain triglycerides

rice starch

silicon dioxide

sucrose

thaumatin

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