



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	330844	Calcium & Magnesium Plus K2 & D3
ARTG entry for	Medicine Listed	
Sponsor	NRC Nutrition Pty Ltd	
Postal Address	PO Box 1248, Coolum Beach, QLD, 4573 Australia	
ARTG Start Date	5/03/2020	
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 . Calcium & Magnesium Plus K2 & D3

Product Type	Single Medicine Product	Effective Date	20/10/2020
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Permitted Indications

- Maintain/support healthy teeth
- Maintain/support bone health
- Aids/assists healthy bone development/growth/building
- Maintain/support (state mineral) absorption in bones
- Helps enhance/promote bone strength
- Helps enhance/promote 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
- Maintain/support cardiovascular system health
- Maintain/support artery health
- Maintain/support immune system health
- Decrease/reduce/relieve muscle cramps
- Helps decrease/reduce/relieve mild muscle spasms/twitches
- Maintain/support healthy muscle contraction function
- Maintain/support muscle relaxation
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support nervous system health
- Maintain/support nervous system function
- Decrease/reduce/relieve symptoms of premenstrual tension
- Maintain/support healthy pregnancy

Indication Requirements

- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to serious immunological diseases.
- 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.

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Product presentation must not imply or refer to serious cardiovascular 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: [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 directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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.

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).

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

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Powder, oral

Route of Administration Oral

Visual Identification

Active Ingredients

calcium citrate	207.47 mg/g
Equivalent: calcium	50.04 mg/g
calcium phosphate	132.3371 mg/g
colecalfiferol	.0025 mg/g
magnesium citrate	308.64 mg/g
Equivalent: magnesium	50 mg/g
menaquinone 7	6 microgram/g

Other Ingredients (Excipients)

- Acacia
- colloidal anhydrous silica
- d-alpha-tocopherol
- Flavour
- fractionated coconut oil
- lecithin
- liquid glucose
- malic acid
- maltodextrin
- silicon dioxide
- sodium ascorbate
- thaumatin

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