



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	375466	Calcium & Magnesium Plus K2 & D3
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	NRC Nutrition Pty Ltd	
<b>Postal Address</b>	PO Box 380, Peregian Beach, QLD, 4573 Australia	
<b>ARTG Start Date</b>	29/09/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	29/09/2021
---------------------	-------------------------	-----------------------	------------

### 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

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 circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must not imply or refer to mental illnesses, disorders or 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



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

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).

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

Product presentation must not imply or refer to serious cardiovascular 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.

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

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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 immunological diseases.

**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**

**Components**

**1 . Formulation 1**

**Dosage Form** Powder, oral

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>calcium citrate</b>	<b>207.47 mg/g</b>
Equivalent: calcium	50 mg/g
<b>calcium phosphate</b>	<b>132.1528 mg/g</b>
Equivalent: calcium	50 mg/g
<b>colecalfiferol</b>	<b>.0025 mg/g</b>
<b>glycine</b>	<b>85 mg/g</b>
<b>magnesium citrate</b>	<b>308.64 mg/g</b>
Equivalent: magnesium	50 mg/g
<b>menaquinone 7</b>	<b>6 microgram/g</b>

**Other Ingredients (Excipients)**

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

Public Summary



**Australian Government**

**Department of Health and Aged Care**

Therapeutic Goods Administration

---

© 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>.

Public Summary