



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

## Public Summary

<b>Summary for ARTG Entry:</b>	383877	Calcium K2 with D3
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Herbs of Gold Pty Ltd	
<b>Postal Address</b>	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
<b>ARTG Start Date</b>	11/02/2022	
<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 K2 with D3

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	11/02/2022
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#### Permitted Indications

- Maintain/support healthy teeth
- Maintain/support teeth mineralisation
- Maintain/support bone health
- Maintain/support bone health in post-menopausal women
- Maintain/support bone mass/density/integrity in post-menopausal women
- Maintain/support bone mass/density/integrity
- Maintain/support (state mineral) absorption in bones
- Maintain/support bone strength in post-menopausal women
- 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
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function

#### 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.

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.

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 serious cardiovascular conditions.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications



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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** Tablet, film coated

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

calcified lithothamnion tophiforme	395.8365 mg
calcium citrate tetrahydrate	611.4 mg
Equivalent: calcium	125 mg
colecalfiferol	.0083 mg
menaquinone 7	.015 mg

**Other Ingredients (Excipients)**

Acacia  
calcium carbonate  
calcium phosphate  
croscarmellose sodium  
dl-alpha-tocopherol  
hypromellose  
isomalt  
magnesium stearate  
maize starch  
medium chain triglycerides  
microcrystalline cellulose  
povidone  
silicon dioxide  
sodium ascorbate  
starch sodium octenyl succinate  
sucrose

Public Summary

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