



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

## Public Summary

<b>Summary for ARTG Entry:</b>	384254	Calcifediol-D
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Bio-Practica Pty Ltd	
<b>Postal Address</b>	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia	
<b>ARTG Start Date</b>	18/02/2022	
<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 . Calcifediol-D

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	18/02/2022
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### Permitted Indications

Maintain/support general health and wellbeing  
Maintain/support healthy teeth  
Maintain/support bone health  
Aids/assists healthy bone development/growth/building  
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 heart health  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support muscle health  
Maintain/support muscle function  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Maintain/support neuromuscular function  
Maintain/support nervous system health

### Indication Requirements

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

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 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.

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 serious immunological diseases.

Product presentation must not imply or refer to serious cardiovascular conditions.

If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is



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inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).

**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. The medicine should not be taken in combination with supplements containing Vitamin D without medical advice (or words to that effect). Calcifediol may have similar effects to Vitamin D. Consult your health care professional before taking in combination with other medicines. Use in children under 9 years is not recommended.

**Additional Product information**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, uncoated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

calcifediol monohydrate	.01 mg
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**Other Ingredients (Excipients)**

- calcium hydrogen phosphate dihydrate
- croscarmellose sodium
- crospovidone
- dl-alpha-tocopherol
- magnesium stearate
- medium chain triglycerides
- microcrystalline cellulose
- silicon dioxide
- sodium ascorbate
- starch sodium octenyl succinate
- sucrose

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Public Summary