



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	354356	Vitamin D + Bone + Heart Health
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	JSHealth Vitamins Pty Ltd	
<b>Postal Address</b>	14/409 New South Head Road, Double Bay, Sydney, NSW, 2028 Australia	
<b>ARTG Start Date</b>	5/02/2021	
<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 . Vitamin D + Bone + Heart Health

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/02/2021
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### Permitted Indications

Maintain/support general health and wellbeing  
Maintain/support healthy teeth  
Maintain/support teeth mineralisation  
Maintain/support teeth strength  
Maintain/support bone health  
Aids/assists healthy bone development/growth/building  
Maintain/support bone mass/density/integrity  
Maintain/support (state mineral) absorption in bones  
Maintain/support bone strength  
Help maintain/support bone mineralisation  
Helps maintain/support healthy blood sugar/glucose  
Maintain/support cardiovascular system health  
Maintain/support healthy cardiovascular system function  
Maintain/support heart health  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support immune system to fight illness  
Maintain/support muscle health  
Maintain/support muscle strength  
Aid/assist/helps glucose/sugar/carbohydrate metabolism  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Maintain/support brain function  
Maintain/support brain health  
Maintain/support skin health

### Indication Requirements

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



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Product presentation must not imply or refer to serious immunological diseases.

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.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

**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**

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

**1 . Formulation 1**

**Dosage Form**                      Capsule, soft

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

colecalfiferol	25 microgram
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**Other Ingredients (Excipients)**

- d-alpha-tocopherol
- fractionated coconut oil
- glycerol
- modified food starch
- purified water
- Rice bran oil
- sorbitol
- vanillin

Public Summary

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