



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

## Public Summary

<b>Summary for ARTG Entry:</b>	330437	Adult Vita Gummies Multivitamin
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Pharmacare Laboratories Pty Ltd	
<b>Postal Address</b>	PO Box 384, MONA VALE, NSW, 1660 Australia	
<b>ARTG Start Date</b>	26/02/2020	
<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 . Adult Vita Gummies Multivitamin

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/12/2022
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#### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support collagen formation
- Maintain/support collagen health
- Maintain/support energy levels
- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support healthy teeth
- Maintain/support nail health/strength/thickness
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health
- Maintain/support (state mineral) absorption in bones
- Maintain/support bone strength
- Help maintain/support bone mineralisation
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood health
- Maintain/support cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support heart health
- Maintain/support healthy thyroid gland function
- Maintain/support thyroid gland health
- Aid/assist thyroid hormone production

Public Summary



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 Therapeutic Goods Administration

Maintain/support immune system health  
 Maintain/support healthy immune system function  
 Maintain/support healthy muscle contraction function when sun exposure is inadequate  
 Maintain/support muscle health when sun exposure is inadequate  
 Maintain/support muscle function when sun exposure is inadequate  
 Helps decrease/reduce homocysteine levels  
 Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)  
 Maintain/support absorption of dietary (state vitamin/mineral/nutrient)  
 Maintain/support (state vitamin/mineral/nutrient) levels in the body  
 Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)  
 Aid/assist/helps synthesis of neurotransmitters  
 Maintain/support nervous system health  
 Maintain/support nervous system function  
 Maintain/support skin health

**Indication Requirements**

Product presentation must not imply or refer to serious immunological diseases.  
 Product presentation must not imply or refer to any thyroid related 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.  
 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 cardiovascular conditions.  
 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).  
 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 chronic fatigue syndrome.  
 If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.  
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

**Additional Product information**

**Pack Size/Poison information**

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

**1 . Formulation 1**

<b>Dosage Form</b>	Pastille
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

ascorbic acid	20 mg
Biotin	8.7 microgram
calcium phosphate	13.33 mg
Equivalent: calcium	5 mg
colecalfiferol	.0025 mg



Australian Government  
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<b>cyanocobalamin</b>	<b>.75 microgram</b>
<b>dibasic magnesium phosphate trihydrate</b>	<b>35.87 mg</b>
Equivalent: magnesium	5 mg
<b>dl-alpha-tocopheryl acetate</b>	<b>3.5 mg</b>
<b>nicotinamide</b>	<b>6 mg</b>
<b>potassium iodide</b>	<b>29 microgram</b>
Equivalent: iodine	22.5 microgram
<b>pyridoxine hydrochloride</b>	<b>608 microgram</b>
Equivalent: pyridoxine	500 microgram
<b>riboflavin</b>	<b>125 microgram</b>
<b>thiamine nitrate</b>	<b>350 microgram</b>
<b>zinc oxide</b>	<b>1.28 mg</b>
Equivalent: zinc	1 mg

**Other Ingredients (Excipients)**

Acacia  
ascorbic acid  
calcium phosphate  
Carnauba Wax  
citric acid  
Colour  
dibutyl sebacate  
dl-alpha-tocopherol  
ethylcellulose  
Flavour  
fractionated coconut oil  
Gelatin  
glycerol  
liquid glucose  
maize starch  
malic acid  
medium chain triglycerides  
potable water  
purified water  
silicon dioxide  
starch sodium octenyl succinate  
sucrose  
vegetable oil

Public Summary

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