



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	376257	Hivita Wellness WOMEN'S MULTIVITAMIN
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Hivita Wellness Pty Ltd	
<b>Postal Address</b>	Level 1 60 Toorak Road, South Yarra, VIC, 3141 Australia	
<b>ARTG Start Date</b>	13/10/2021	
<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 . Hivita Wellness WOMEN'S MULTIVITAMIN**

Product Type	Effective Date
Single Medicine Product	13/10/2021

**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Helps enhance/promote collagen formation
- Maintain/support collagen formation
- Maintain/support collagen health
- Enhance/promote energy levels
- Maintain/support energy levels
- Maintain/support physical endurance/capacity/stamina
- Helps enhance/promote body energy reserves
- Helps enhance/promote/increase vitality
- Maintain/support vitality
- Maintain/support eye health
- Helps enhance/promote general health and wellbeing
- Maintain/support general health and wellbeing
- Maintain/support connective tissue health
- Helps enhance/promote connective tissue health
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Helps maintain/support healthy heart function
- Maintain/support healthy thyroid gland function
- Maintain/support immune system health
- Enhance/improve/promote immune defence/immunity
- Helps enhance/improve/promote immune system function
- Maintain/support healthy immune system function
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Support healthy stress response in the body
- Help maintain/support emotional wellbeing

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Maintain/support cognitive function/mental function  
 Maintain/support reproductive system health  
 Aphrodisiac/Enhance/improve/promote healthy libido  
 Maintain/support healthy libido

**Indication Requirements**

Product presentation must not imply or refer to chronic fatigue syndrome.

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 infertility.

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 any thyroid related diseases.

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 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 cardiovascular conditions.

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

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

**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, hard

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>37.5 mg</b>
<b>Biotin</b>	<b>50 microgram</b>
<b>calcium citrate tetrahydrate</b>	<b>77.5 mg</b>
Equivalent: calcium	16.35 mg
<b>calcium pantothenate</b>	<b>22.5 mg</b>
Equivalent: pantothenic acid	20.61 mg
Equivalent: calcium	1.89 mg
<b>chromium picolinate</b>	<b>48.3 microgram</b>
Equivalent: chromium	6 microgram
<b>colecalfiferol</b>	<b>.0037 mg</b>
<b>d-alpha-tocopheryl acid succinate</b>	<b>12.39 mg</b>
<b>folic acid</b>	<b>125 microgram</b>

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<b>iron amino acid chelate</b>	<b>37.5 mg</b>
Equivalent: iron	3.75 mg
<b>Lepidium meyenii tuber Extract dry concentrate</b>	<b>75 mg</b>
Equivalent: Lepidium meyenii (Dry)	750 mg
<b>magnesium amino acid chelate</b>	<b>75 mg</b>
Equivalent: magnesium	15 mg
<b>manganese amino acid chelate</b>	<b>7.5 mg</b>
Equivalent: manganese	750 microgram
<b>mecobalamin</b>	<b>150 microgram</b>
<b>nicotinamide</b>	<b>17.5 mg</b>
<b>phytomenadione</b>	<b>7.5 microgram</b>
<b>potassium iodide</b>	<b>48.8 microgram</b>
Equivalent: iodine	36.5 microgram
Equivalent: potassium	11.3 microgram
<b>pyridoxine hydrochloride</b>	<b>15.19 mg</b>
Equivalent: pyridoxine	12.5 mg
<b>retinol acetate</b>	<b>.207 mg</b>
Equivalent: vitamin A	.1755 mg
<b>riboflavin</b>	<b>12.5 mg</b>
<b>selenomethionine</b>	<b>62.1 microgram</b>
Equivalent: selenium	25 microgram
<b>thiamine hydrochloride</b>	<b>16.82 mg</b>
Equivalent: thiamine	15 mg
<b>Withania somnifera root Extract dry concentrate</b>	<b>7.5 mg</b>
Equivalent: Withania somnifera (Dry)	750 mg
<b>zinc amino acid chelate</b>	<b>15 mg</b>
Equivalent: zinc	3 mg
<b>Zingiber officinale root Extract dry concentrate</b>	<b>10 mg</b>
Equivalent: Zingiber officinale (Dry)	200 mg

**Other Ingredients (Excipients)**

Acacia  
calcium hydrogen phosphate dihydrate  
chlorophyllin-copper complex  
colloidal anhydrous silica  
croscarmellose sodium  
d-alpha-tocopherol  
dl-alpha-tocopherol  
ethylcellulose  
fractionated coconut oil  
hypromellose  
liquid glucose  
magnesium stearate  
maize starch  
maltodextrin  
microcrystalline cellulose  
purified water  
silicon dioxide  
sodium ascorbate  
spray-dried glucose syrup  
sucrose

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