



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	376093	Hivita Wellness MEN'S MULTIVITAMIN
ARTG entry for	Medicine Listed	
Sponsor	Hivita Wellness Pty Ltd	
Postal Address	Level 1 60 Toorak Road, South Yarra, VIC, 3141 Australia	
ARTG Start Date	11/10/2021	
Product Category	Medicine	
Status	Active	
Approval Area	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 MEN'S MULTIVITAMIN

Product Type	Single Medicine Product	Effective Date	11/10/2021
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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
- Helps convert (state food) into energy
- Enhance/promote/physical endurance/capacity/stamina
- 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
- Maintain/support healthy thyroid gland function
- Helps enhance/promote healthy liver function
- Maintain/support healthy liver function
- Maintain/support liver health
- Maintain/support immune system health
- Enhance/improve/promote immune defence/immunity
- Helps enhance/improve/promote immune system function
- Maintain/support healthy immune system function

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Maintain/support (state vitamin/mineral/nutrient) levels in the body
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
 Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
 Aids/assists the body to cope with environmental stress
 Support healthy body stress recovery
 Support healthy stress response in the body
 Support healthy stress response in the body
 Maintain/support reproductive system health
 Helps maintain/support testosterone formation/synthesis
 Help maintain/support healthy prostate function
 Helps enhance/promote prostate health
 Maintain/support prostate health
 Maintain/support sperm health
 Maintain/support sperm motility
 Maintain/support sperm production
 Maintain/support testosterone level

Indication Requirements

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

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.

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 mental illnesses, disorders or conditions.
 Product presentation must not imply or refer to serious genitourinary conditions like Benign Prostatic Hypertrophy, erectile dysfunction or hormone therapy.
 Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

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 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

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.
 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.
 The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

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Active Ingredients

ascorbic acid	45 mg
Biotin	62.5 microgram
calcium citrate tetrahydrate	59.24 mg
Equivalent: calcium	12.5 mg
calcium pantothenate	13.65 mg
Equivalent: pantothenic acid	12.5 mg
Equivalent: calcium	1.45 mg
chromium picolinate	70.4 microgram
Equivalent: chromium	9 microgram
colecalfiferol	1.875 microgram
copper gluconate	42.9 microgram
Equivalent: copper	6 microgram
d-alpha-tocopheryl acid succinate	12.39 mg
Epimedium sagittatum herb top Extract dry concentrate	37.5 mg
Equivalent: Epimedium sagittatum (Dry)	750 mg
folic acid	125 microgram
iron amino acid chelate	18.75 mg
Equivalent: iron	1.88 mg
magnesium amino acid chelate	52.5 mg
Equivalent: magnesium	10.5 mg
manganese amino acid chelate	5.63 mg
Equivalent: manganese	563 microgram
mecobalamin	150 microgram
nicotinamide	15 mg
phytomenadione	8.75 microgram
potassium iodide	49.1 microgram
Equivalent: iodine	38 microgram
Equivalent: potassium	11.6 microgram
pyridoxine hydrochloride	12.15 mg
Equivalent: pyridoxine	10 mg
retinol acetate	.2656 mg
Equivalent: vitamin A	.2252 mg
riboflavin	12.5 mg
selenomethionine	37.3 microgram
Equivalent: selenium	15 microgram
Serenoa repens fruit Extract dry concentrate	7.5 mg
Equivalent: Serenoa repens (Dry)	750 mg
Silybum marianum fruit Extract dry concentrate	10.71 mg
Equivalent: Silybum marianum (Dry)	750 mg
thiamine hydrochloride	14.55 mg
Equivalent: thiamine	12.98 mg
Withania somnifera root Extract dry concentrate	75 mg
Equivalent: Withania somnifera (Dry)	937.5 mg
zinc amino acid chelate	22.5 mg
Equivalent: zinc	4.5 mg

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
chlorophyllin-copper complex

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colloidal anhydrous silica
croscarmellose sodium
d-alpha-tocopherol
dl-alpha-tocopherol
ethylcellulose
fractionated coconut oil
hypromellose
liquid glucose
magnesium stearate
maize starch
microcrystalline cellulose
purified water
silicon dioxide
sodium ascorbate
spray-dried glucose syrup
sucrose

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