



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	302106	Opti Vital Multivitamin
ARTG entry for	Medicine Listed	
Sponsor	Factors Group Australia Pty Ltd	
Postal Address	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
ARTG Start Date	20/04/2018	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Opti Vital Multivitamin

Product Type	Single Medicine Product	Effective Date	18/06/2018
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Permitted Indications

- Maintain/support heat/energy production/thermogenesis
- Maintain/support general health and wellbeing
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency

Indication Requirements

- Label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.
- 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).

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.
- Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
- 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.

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If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.
 WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Tablet, film coated
Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	120 mg
betacarotene	1.98 mg
Biotin	60 microgram
borax	529.1 microgram
Equivalent: boron	60 microgram
calcium folinate	270.1 microgram
Equivalent: folic acid	250 microgram
calcium hydrogen phosphate dihydrate	627.778 mg
Equivalent: phosphorus	113 mg
Equivalent: calcium	135 mg
calcium pantothenate	10.917 mg
Equivalent: pantothenic acid	10 mg
calcium phosphate	91.892 mg
Equivalent: phosphorus	17 mg
Equivalent: calcium	30 mg
chromium picolinate	402.252 microgram
Equivalent: chromium	50 microgram
colecalfiferol	.01 mg
cupric oxide	4.381 mg
Equivalent: copper	3.5 mg
d-alpha-tocopheryl acetate	22.06 mg
ferrous fumarate	15.197 mg
Equivalent: iron	5 mg
heavy magnesium oxide	82.912 mg
Equivalent: magnesium	50 mg
lutein	250 microgram
lycopene	.3 mg
manganese sulfate monohydrate	23.077 mg
Equivalent: manganese	7.5 mg
mecobalamin (co-methylcobalamin)	100 microgram
molybdenum trioxide	112.528 microgram
Equivalent: molybdenum	75 microgram
nicotinic acid	50 mg
Panax ginseng root Extract dry concentrate standardised	55 mg
Equivalent: Panax ginseng (Dry)	220 mg
phytomenadione	.08 mg
potassium citrate	276 mg

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Equivalent: potassium	100 mg
potassium iodide	196.335 microgram
Equivalent: iodine	150 microgram
pyridoxal 5-phosphate monohydrate	16.234 mg
Equivalent: pyridoxine	10 mg
retinol acetate	.5865 mg
riboflavin	6 mg
selenomethionine	372.578 microgram
Equivalent: selenium	150 microgram
silicon dioxide	8.565 mg
Equivalent: silicon	4 mg
sodium chloride	148.368 mg
Equivalent: chloride	90 mg
thiamine nitrate	6.476 mg
Equivalent: thiamine	5.25 mg
zinc oxide	18.68 mg
Equivalent: zinc	15 mg

Other Ingredients (Excipients)

Acacia
butylated hydroxytoluene
calcium hydrogen phosphate dihydrate
calcium phosphate
calcium silicate
croscarmellose sodium
dl-alpha-tocopherol
Gelatin
glucose monohydrate
glycerol
hypromellose
magnesium stearate
Maize Oil
maize starch
medium chain triglycerides
microcrystalline cellulose
Pisum sativum
purified water
silicon dioxide
sodium alginate
sodium ascorbate
starch sodium octenyl succinate
sucrose

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