



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	323097	Men's 50+ Multi
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	12/09/2019	
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 . Men's 50+ Multi

Product Type	Single Medicine Product	Effective Date	12/09/2019
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support healthy eye function
- Maintain/support eye health
- Maintain/support healthy eyesight/vision
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Maintain/support nail health/strength/thickness
- Maintain/support bone 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 cardiovascular system health
- Maintain/support healthy cardiovascular system function
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle health
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support (state vitamin/mineral) within normal range
- Maintain/support cognitive function/mental function

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Maintain/support memory/mental recall
 Maintain/support brain health
 Maintain/support skin health

Indication Requirements

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

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

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 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 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).

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

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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

Apium graveolens seed Extract dry concentrate	2.25 mg
Equivalent: Apium graveolens (Dry)	22.5 mg
Apium graveolens herb top Extract dry concentrate	200 microgram
Equivalent: Apium graveolens (Fresh)	3 mg
Arthrospira platensis	5 mg
Ascophyllum nodosum whole plant Powder standardised	18.75 mg
betacarotene	3 mg
Beta vulgaris root Powder	2.25 mg
Beta vulgaris root Extract dry concentrate	178 microgram
Equivalent: Beta vulgaris (Fresh)	1.78 mg
borax	6.579 mg
Equivalent: boron	750 microgram
Brassica oleracea var. botrytis herb top Powder	3.75 mg
Brassica oleracea var. botrytis herb top Extract dry concentrate	181 microgram
Equivalent: Brassica oleracea var. botrytis (Fresh)	2.715 mg

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Brassica oleracea var. capitata leaf Powder	3.75 mg
Brassica oleracea var. capitata herb top Extract dry concentrate	368 microgram
Equivalent: Brassica oleracea var. capitata (Fresh)	16.56 mg
Brassica oleracea var. italica herb top Powder	3.75 mg
Brassica oleracea var. viridis herb top Powder	2.25 mg
Brassica oleracea var. viridis leaf Extract dry concentrate	33 microgram
Equivalent: Brassica oleracea var. viridis (Fresh)	132 microgram
calcified lithothamnion species	28.722 mg
Equivalent: calcium	8.616 mg
Equivalent: magnesium	631.9 microgram
calcium ascorbate	38.584 mg
Equivalent: ascorbic acid	32.5 mg
Equivalent: calcium	3.883 mg
calcium pantothenate	5.458 mg
Equivalent: pantothenic acid	5 mg
Camellia sinensis leaf Extract dry concentrate	5 mg
Equivalent: Camellia sinensis (Dry)	150 mg
Capsicum annuum fruit Extract dry concentrate	260 microgram
Equivalent: Capsicum annuum (Fresh)	5.2 mg
Chlorella vulgaris whole plant Powder	5 mg
chromium picolinate	201.1263 microgram
Equivalent: chromium	25 microgram
Citrus sinensis fruit Extract dry concentrate	5 mg
Equivalent: Citrus sinensis (Dry)	1.75 g
colecalfiferol	.0125 mg
Coriandrum sativum leaf Powder	2.25 mg
Coriandrum sativum leaf Extract dry concentrate	16 microgram
Equivalent: Coriandrum sativum (Fresh)	16 microgram
cupric sulfate	2 mg
Equivalent: copper	200 microgram
curcumin	.5 mg
Cynara scolymus leaf Powder	2.25 mg
Cynara scolymus flower bud Extract dry	1 microgram
Equivalent: Cynara scolymus (Fresh)	149.9 ng
d-alpha-tocopherol	10 mg
Echinacea purpurea herb top Extract dry concentrate	88 microgram
Equivalent: Echinacea purpurea (Fresh)	616 microgram
Eruca sativa leaf Powder	3.75 mg
Euterpe oleracea fruit Juice powder	5 mg
Fragaria vesca fruit Powder	250 microgram
Hordeum vulgare leaf Powder	2.25 mg
Laminaria digitata whole plant Powder	5 mg
Laminaria japonica whole plant Powder	360 microgram
levomefolate glucosamine	462.963 microgram
Equivalent: levomefolic acid	250 microgram
lutein	1 mg
lycopene	1 mg
Lycopersicon esculentum fruit Powder	2.25 mg
Lycopersicon esculentum fruit Extract dry concentrate	133 microgram
Equivalent: Lycopersicon esculentum (Fresh)	399 microgram
magnesium ascorbate	45.5 mg



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Equivalent: ascorbic acid	32.5 mg
Equivalent: magnesium	4.55 mg
magnesium aspartate	19.875 mg
Equivalent: magnesium	3.975 mg
magnesium citrate	24.537 mg
Equivalent: magnesium	3.975 mg
manganese gluconate	43.86 mg
Equivalent: manganese	5 mg
mecobalamin	200 microgram
Medicago sativa leaf Extract dry concentrate	1.713 mg
Equivalent: Medicago sativa (Fresh)	42.825 mg
menaquinone 7	40 microgram
Mentha spicata herb top Extract dry concentrate	74 microgram
Equivalent: Mentha spicata (Fresh)	592 microgram
Mentha X piperita herb top Extract dry concentrate	206 microgram
Equivalent: Mentha X piperita (Fresh)	1.854 mg
Nasturtium officinale leaf Powder	2.5 mg
Nasturtium officinale leaf Extract dry	9 microgram
Equivalent: Nasturtium officinale (Fresh)	7.2 microgram
nicotinamide	12.5 mg
Origanum vulgare herb top Extract dry concentrate	39 microgram
Equivalent: Origanum vulgare (Fresh)	156 microgram
Petroselinum crispum leaf Powder	2.25 mg
Petroselinum crispum herb top Extract dry concentrate	771 microgram
Equivalent: Petroselinum crispum (Fresh)	15.42 mg
Phyllanthus emblica fruit Extract dry concentrate standardised	65 mg
Equivalent: Phyllanthus emblica (Dry)	3.25 g
Phyllanthus emblica fruit Extract dry concentrate standardised	10 mg
Equivalent: Phyllanthus emblica (Dry)	500 mg
Punica granatum fruit Powder	250 microgram
pyridoxal 5-phosphate monohydrate	2.03 mg
Equivalent: pyridoxine	1.25 mg
Raphanus sativus root Powder	7.5 mg
Raphanus sativus root Powder	2.25 mg
riboflavin sodium phosphate	1.7093 mg
Equivalent: riboflavin	1.25 mg
Rubus idaeus fruit Powder	250 microgram
Schisandra chinensis fruit Extract dry concentrate	5 mg
Equivalent: Schisandra chinensis (Dry)	100 mg
selenomethionine	124.18 microgram
Equivalent: selenium	50 microgram
Serenoa repens fruit Extract dry concentrate	25 mg
Equivalent: Serenoa repens (Fresh)	200 mg
Silybum marianum seed Extract dry concentrate	5 mg
Equivalent: Silybum marianum (Dry)	125 mg
Taraxacum officinale root Powder	2.25 mg
thiamine hydrochloride	6.355 mg
Equivalent: thiamine	5 mg
Vaccinium macrocarpon fruit Powder	5 mg
Vaccinium macrocarpon fruit Powder	250 microgram



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Vaccinium myrtillus fruit Powder	250 microgram
Vitis vinifera seed Extract dry concentrate	21.5 mg
Equivalent: Vitis vinifera (Dry)	795.5 mg
Vitis vinifera seed Extract dry concentrate	2 mg
Equivalent: Vitis vinifera (Dry)	200 mg
zinc citrate	36.6 mg
Equivalent: zinc	12.5 mg
Zingiber officinale root Extract dry concentrate	5 mg
Equivalent: Zingiber officinale (Dry)	125 mg

Other Ingredients (Excipients)

Acacia
ascorbic acid
ascorbyl palmitate
calcium hydrogen phosphate
chlorophyllin-copper complex
citric acid
colloidal anhydrous silica
croscarmellose sodium
d-alpha-tocopherol
dl-alpha-tocopherol
Gelatin
Ghatti Gum
glucose
glycerol
hydrolysed maize starch
hypromellose
magnesium stearate
maize starch
maltodextrin
maltose
microcrystalline cellulose
mixed (high-alpha type) tocopherols concentrate
mixed (low-alpha type) tocopherols concentrate
mono- and di- glycerides
potable water
pregelatinised maize starch
silicon dioxide
sodium ascorbate
Soya Oil
starch sodium octenyl succinate
stearic acid
sucrose

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