



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	323097	Men's 50+ Multi
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Factors Group Australia Pty Ltd	
<b>Postal Address</b>	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
<b>ARTG Start Date</b>	12/09/2019	
<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.

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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	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

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 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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

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.

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.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

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.

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

#### 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

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



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



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



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

Public Summary

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