

Department of Health

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 323608 Women'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 16/09/2019
Product Category Medicine
Status Active

Approval Area Listed Medicines

Conditions

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 . Women's 50+ Multi

Product Type Single Medicine Product Effective Date 16/09/2019

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

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

Maintain/support memory/mental recall

Maintain/support brain health

Maintain/support skin health

Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.

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

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 immunological diseases.

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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 vision correction, faults or serious eye disease e.g. macular degeneration.

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.

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).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Adults only.

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			
	Cina/Daia	:	_

Pack Size Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

alpha lipoic acid25 mgApium graveolens seed Extract dry concentrate2.25 mgEquivalent: 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 Powder 2.25 mg

Beta vulgaris root Extract dry concentrate 178 microgram

 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 Extract dry concentrate 181 microgram

Equivalent: Brassica oleracea var. botrytis (Fresh)

2.715 mg

Brassica oleracea var. botrytis herb top Powder

3.75 mg

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)

calcified lithothamnion species

33 microgram

132 microgram

63.04 mg

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Equivalent: calcium	18.912 mg
Equivalent: magnesium	1.36 mg
calcium ascorbate	60.49 mg
Equivalent: calcium	6.088 mg
Equivalent: ascorbic acid	50 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: Cansicum annuum (Fresh)	5.2 ma

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

 colecalciferol
 .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) 598.8 ng

 d-alpha-tocopherol
 10 mg

 Echinacea purpurea herb top Extract dry concentrate
 88 microgram

 Equivalent: Echinacea purpurea (Fresh)
 616 microgram

Eruca sativa leaf Powder3.75 mgEuterpe oleracea fruit Juice powder5 mgFragaria vesca fruit Powder250 microgramHordeum vulgare leaf Powder2.25 mg

Laminaria japonica whole plant Powder 360 microgram levomefolate glucosamine 462.963 microgram

Equivalent: levomefolic acid250 microgramIutein1 mglycopene1 mg

 Lycopersicon esculentum fruit Extract dry concentrate
 133 microgram

 Equivalent: Lycopersicon esculentum (Fresh)
 399 microgram

 Lycopersicon esculentum fruit Powder
 2.25 mg

magnesium ascorbate 38.92 mg Equivalent: ascorbic acid 27.827 mg Equivalent: magnesium 3.892 mg 18.215 mg magnesium aspartate Equivalent: magnesium 3.643 mg magnesium citrate 18.92 mg Equivalent: magnesium 3.065 mg manganese gluconate 10.965 mg Equivalent: manganese

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5 mg

Laminaria digitata whole plant Powder



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mecobalamin (co-methylcobalamin)	
Medicago sativa leaf Extract dry concentrate	

Equivalent: Medicago sativa (Fresh)

menaquinone 7

Mentha spicata herb top Extract dry concentrate

Equivalent: Mentha spicata (Fresh)

Mentha X piperita herb top Extract dry concentrate

Equivalent: Mentha X piperita (Fresh)

Nasturtium officinale leaf Extract dry

Equivalent: Nasturtium officinale (Fresh)

Nasturtium officinale leaf Powder

nicotinamide

Origanum vulgare herb top Extract dry concentrate

Equivalent: Origanum vulgare (Fresh)

Petroselinum crispum leaf Powder

Petroselinum crispum herb top Extract dry concentrate

Equivalent: Petroselinum crispum (Fresh)

Phyllanthus emblica fruit Extract dry concentrate

Equivalent: Phyllanthus emblica (Dry)

Phyllanthus emblica fruit Extract dry concentrate standardised

Equivalent: Phyllanthus emblica (Dry)

Punica granatum fruit Powder

pyridoxal 5-phosphate monohydrate

Equivalent: pyridoxine

Raphanus sativus root Powder Raphanus sativus root Powder riboflavin sodium phosphate

Equivalent: riboflavin

Rubus idaeus fruit Powder

Schisandra chinensis fruit Extract dry concentrate

Equivalent: Schisandra chinensis (Dry)

selenomethionine

Equivalent: selenium

Silybum marianum seed Extract dry concentrate

Equivalent: Silybum marianum (Dry)

Taraxacum officinale root Powder

thiamine hydrochloride
Equivalent: thiamine

Vaccinium macrocarpon fruit Powder

Vaccinium macrocarpon fruit Powder
Vaccinium myrtillus fruit Powder

Vitis vinifera seed Extract dry concentrate

Equivalent: Vitis vinifera (Dry)

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Vitis vinifera seed Extract dry concentrate

Equivalent: Vitis vinifera (Dry)
zinc citrate

Zingiber officinale root Extract dry concentrate

Equivalent: Zingiber officinale (Dry)

1.25 mg

200 microgram

1.713 mg

42.825 mg

40 microgram

74 microgram

592 microgram

206 microgram

1.854 mg

9 microgram

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7.2 microgram

2.5 mg

12.5 mg

39 microgram156 microgram

2.25 mg

771 microgram

15.42 mg

10 mg

500 mg

9.346 mg

467.3 ma

407.5 mg

250 microgram

2.03 mg

1.25 mg

2.25 mg 7.5 mg

1.7093 mg

1.25 mg

250 microgram

5 mg

100 mg

124.18 microgram

50 microgram

5 mg

125 mg

2.25 mg

6.355 mg

5 mg

250 microgram

5 mg

250 microgram

21.5 mg 795.5 mg

2 mg

200 mg

.oo mg

21.962 mg

7.5 mg

5 mg

125 mg

Equivalent: zinc



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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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