



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|-----------------|
| Summary for ARTG Entry: | 313242 | Women's Multi + |
| ARTG entry for | Medicine Listed | |
| Sponsor | Herbs of Gold Pty Ltd | |
| Postal Address | PO Box 3143, KIRRAWEE, NSW, 2232 Australia | |
| ARTG Start Date | 14/01/2019 | |
| 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 . Women's Multi +

| Product Type | Single Medicine Product | Effective Date | 21/11/2019 |
|--------------|-------------------------|----------------|------------|
|--------------|-------------------------|----------------|------------|

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Maintain/support collagen health
- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support bone health in post-menopausal women
- Maintain/support bone health
- Maintain/support bone health
- Maintain/support bone mass/density/integrity in post-menopausal women
- Maintain/support bone mass/density/integrity
- Maintain/support bone strength in post-menopausal women
- Maintain/support bone strength
- Help maintain/support bone mineralisation
- Vitamin D helps calcium absorption (or words of like intent) and a diet deficient in calcium can lead to osteoporosis in later life
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health

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- Maintain/support blood health
- Maintain/support healthy thyroid gland function
- Maintain/support healthy thyroid hormones
- Maintain/support thyroid gland health
- Aid/assist thyroid hormone production
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support muscle health
- Maintain/support muscle function
- Maintain/support muscle strength
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Support healthy stress response in the body
- Maintain/support cognitive function/mental function
- Maintain/support memory/mental recall
- Maintain/support brain function
- Maintain/support brain health
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support skin health
- Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Product presentation must not imply or refer to any thyroid related diseases.

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

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

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

Label statement: If symptoms persist, talk to your health professional.

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.

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

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.

Additional Product information

Pack Size/Poison information

| | |
|------------------|------------------------|
| Pack Size | Poison Schedule |
|------------------|------------------------|

Components

1 . Formulation 1

| | |
|--------------------------------|---------------------|
| Dosage Form | Tablet, film coated |
| Route of Administration | Oral |



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Visual Identification

Active Ingredients

| | |
|---|----------------------|
| ascorbic acid | 100 mg |
| Biotin | 50 microgram |
| calcium citrate tetrahydrate | 71.09 mg |
| Equivalent: calcium | 15 mg |
| calcium hydrogen phosphate | 169.72 mg |
| Equivalent: calcium | 50 mg |
| calcium pantothenate | 100 mg |
| Equivalent: calcium | 8.39 mg |
| Equivalent: pantothenic acid | 91.6 mg |
| choline bitartrate | 25 mg |
| chromium nicotinate | 417 microgram |
| Equivalent: chromium | 50 microgram |
| Citrus bioflavonoids extract | 50 mg |
| colecalfiferol | .025 mg |
| colloidal anhydrous silica | 42.78 mg |
| Equivalent: silicon | 20 mg |
| copper gluconate | 3.57 mg |
| Equivalent: copper | 500 microgram |
| d-alpha-tocopheryl acid succinate | 41.32 mg |
| Equivalent: d-alpha-tocopheryl acid succinate | 50 IU |
| ferrous fumarate | 16.01 mg |
| Equivalent: iron | 5 mg |
| folic acid | 200 microgram |
| inositol | 25 mg |
| levomefolate calcium | 124 microgram |
| Equivalent: calcium | 9.61 microgram |
| Equivalent: levomefolic acid | 100 microgram |
| magnesium amino acid chelate | 125 mg |
| Equivalent: magnesium | 25 mg |
| manganese amino acid chelate | 10 mg |
| Equivalent: manganese | 1 mg |
| mecobalamin (co-methylcobalamin) | 100 microgram |
| nicotinamide | 50 mg |
| potassium iodide | 196 microgram |
| Equivalent: iodine | 150 microgram |
| Equivalent: potassium | 46 microgram |
| pyridoxine hydrochloride | 60.78 mg |
| Equivalent: pyridoxine | 50 mg |
| riboflavine | 25 mg |
| selenomethionine | 124 microgram |
| Equivalent: selenium | 50 microgram |
| Silybum marianum fruit Extract dry concentrate | 14.29 mg |
| Equivalent: Silybum marianum (Dry) | 1 g |
| thiamine hydrochloride | 25 mg |
| Equivalent: thiamine | 22.3 mg |
| Vitis vinifera seed Extract dry concentrate | 100 mg |
| Equivalent: Vitis vinifera (Dry) | 12 g |
| zinc citrate dihydrate | 31.15 mg |

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Equivalent: zinc

10 mg

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
Carnauba Wax
croscarmellose sodium
crospovidone
d-alpha-tocopherol
ethylcellulose
fractionated coconut oil
hypromellose
iron oxide red
liquid glucose
macrogol 8000
magnesium stearate
microcrystalline cellulose
povidone
silicon dioxide
sodium ascorbate
vanillin

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