



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|--|
| Summary for ARTG Entry: | 347552 | METAGENICS FEMME ESSENTIALS MULTIVITAMIN and MINERAL |
| ARTG entry for | Medicine Listed | |
| Sponsor | Metagenics (Aust) Pty Ltd | |
| Postal Address | PO Box 675, VIRGINIA BC, QLD, 4014 Australia | |
| ARTG Start Date | 6/11/2020 | |
| 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.

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 . METAGENICS FEMME ESSENTIALS MULTIVITAMIN and MINERAL

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 27/06/2022 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body in females
- Maintain/support energy production in females
- Maintain/support bone health in females
- Maintain/support blood health in females
- Maintain/support heart health in females
- Maintain/support muscle function in females
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in females
- Maintain/support cognitive function/mental function in females
- Maintain/support brain function in females
- Maintain/support nervous system function in females
- Decrease/reduce/relieve symptoms of premenstrual tension
- Maintain/support healthy reproductive hormones in females

Indication Requirements

- Product presentation must not imply or refer to serious cardiovascular conditions.
- 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 mental illnesses, disorders or conditions.
- Label statement: If symptoms persist, talk to your health professional.
- 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).
- Product presentation must not imply or refer to hormone imbalances.

Standard Indications

No Standard Indications included on Record

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Specific Indications

No Specific Indications included on Record

Warnings

Not to be taken by children under 2 years old (or words to that effect).

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral 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.

If symptoms persist consult your healthcare practitioner (or words to that effect).

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.
 [Contains vitamin B6].

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 | 50 mg |
| betacarotene | 4 mg |
| Biotin | 50 microgram |
| borax | 26.54 mg |
| Equivalent: boron | 3.01 mg |
| Brassica oleracea var. italica sprout Powder | 100 mg |
| calcium amino acid chelate | 100 mg |
| Equivalent: calcium | 20 mg |
| calcium citrate tetrahydrate | 189.75 mg |
| Equivalent: calcium | 40 mg |
| calcium hydrogen phosphate dihydrate | 171.75 mg |
| Equivalent: calcium | 40 mg |
| calcium pantothenate | 50 mg |
| chromic chloride hexahydrate | 768.84 microgram |
| Equivalent: chromium | 150 microgram |
| colecalfiferol | .0125 mg |
| d-alpha-tocopheryl acid succinate | 25 mg |
| Equivalent: d-alpha-tocopherol | 20.26 mg |
| dibasic potassium phosphate | 77.95 mg |
| Equivalent: potassium | 35 mg |
| folic acid | 400.06 microgram |
| iron amino acid chelate | 25 mg |
| Equivalent: iron | 5 mg |
| magnesium glycinate dihydrate | 100 mg |
| Equivalent: magnesium | 10 mg |
| manganese amino acid chelate | 15.63 mg |
| Equivalent: manganese | 2.5 mg |
| mecobalamin (co-methylcobalamin) | 400 microgram |
| mixed (low-alpha type) tocopherols concentrate | 2.499 mg |
| molybdenum trioxide | 150.04 microgram |

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| Equivalent: molybdenum | 100 microgram |
| nicotinamide | 100 mg |
| phytomenadione | .08 mg |
| potassium iodide | 391.11 microgram |
| Equivalent: iodine | 299 microgram |
| pyridoxal 5-phosphate | 5 mg |
| Equivalent: pyridoxine | 3.19 mg |
| pyridoxine hydrochloride | 40 mg |
| Equivalent: pyridoxine | 32.91 mg |
| riboflavin | 20 mg |
| selenomethionine | 65 microgram |
| Equivalent: selenium | 26 microgram |
| thiamine hydrochloride | 50 mg |
| zinc sulfate monohydrate | 27.55 mg |
| Equivalent: zinc | 10.04 mg |

Other Ingredients (Excipients)

Acacia
calcium hydrogen phosphate dihydrate
calcium hydrogen phosphate
citric acid
croscarmellose sodium
dl-alpha-tocopherol
glycerol
hypromellose
liquid glucose
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
potable water
silicon dioxide
sodium ascorbate
Soya Oil
starch sodium octenyl succinate
sucrose

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