



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|--------------------|
| Summary for ARTG Entry: | 301553 | Women's Essentials |
| ARTG entry for | Medicine Listed | |
| Sponsor | FIT-BioCeuticals Limited | |
| Postal Address | Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia | |
| ARTG Start Date | 3/04/2018 11:00:00 PM | |
| 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.

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 Essentials

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 12/06/2020 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Maintain/support energy levels
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support bone health
- Helps maintain/support healthy blood sugar/glucose
- Maintain/support blood health
- Maintain/support healthy thyroid gland function
- Maintain/support healthy thyroid hormones
- Maintain/support healthy liver function
- Maintain/support healthy immune system function
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Helps decrease/reduce homocysteine levels
- Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)
- Traditionally used in Ayurvedic medicine to adaptogen/Help body adapt to stress
- Maintain/support cognitive function/mental function
- Maintain/support skin health

Indication Requirements

Product presentation must not imply or refer to any thyroid related diseases.
 Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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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 liver disease, such as cirrhosis, hepatitis.

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

Product presentation must not imply or refer to serious immunological 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.

Product presentation must not imply or refer to chronic fatigue syndrome.

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).

If Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

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 and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

WARNING - this medication may be dangerous when used in large amounts or for a long time; or WARNING - this product contains [insert pyridoxine hydrochloride or pyridoxal 5-phosphate as applicable], which may be dangerous when used in large amounts or for a long time.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

Additional Product information

Pack Size/Poison information

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

Components

1 . Formulation 1

| | |
|--------------------------------|---------------|
| Dosage Form | Capsule, hard |
| Route of Administration | Oral |

Visual Identification

Active Ingredients

| | |
|------------------------------|------------------------|
| ascorbic acid | 50 mg |
| Biotin | 75 microgram |
| borax | 8.907 mg |
| Equivalent: boron | 1 mg |
| calcium folinate | 137 microgram |
| Equivalent: folinic acid | 100 microgram |
| calcium pantothenate | 54.6 mg |
| Equivalent: calcium | 4.586 mg |
| Equivalent: pantothenic acid | 50 mg |
| calcium phosphate | 69.44 mg |
| Equivalent: calcium | 25 mg |
| choline bitartrate | 25 mg |
| chromium nicotinate | 192.3 microgram |
| Equivalent: chromium | 25 microgram |
| colecalfiferol | .0124 mg |

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| | |
|---|-------------------------|
| cyanocobalamin | 100 microgram |
| d-alpha-tocopheryl acid succinate | 20.661 mg |
| inositol | 25 mg |
| levomefolate calcium | 130.4 microgram |
| Equivalent: levomefolic acid | 100 microgram |
| Equivalent: calcium | 10.51 microgram |
| magnesium phosphate pentahydrate | 85.366 mg |
| Equivalent: magnesium | 17.5 mg |
| manganese amino acid chelate | 4.44 mg |
| Equivalent: manganese | 1 mg |
| mecobalamin (co-methylcobalamin) | 100 microgram |
| menaquinone 7 | 7.5 microgram |
| molybdenum trioxide | 18.755 microgram |
| Equivalent: molybdenum | 12.5 microgram |
| nicotinamide | 20 mg |
| nicotinic acid | 5 mg |
| potassium iodide | 98.1 microgram |
| Equivalent: iodine | 75 microgram |
| Equivalent: potassium | 23 microgram |
| Punica granatum fruit hull Extract dry concentrate | 12.5 mg |
| Equivalent: Punica granatum (Dry) | 250 mg |
| pyridoxal 5-phosphate monohydrate | 8.117 mg |
| Equivalent: pyridoxine | 5 mg |
| pyridoxine hydrochloride | 24.31 mg |
| Equivalent: pyridoxine | 20 mg |
| retinol palmitate | 682 microgram |
| Equivalent: vitamin A | 375 RE |
| riboflavin | 20 mg |
| riboflavin sodium phosphate | 6.849 mg |
| Equivalent: riboflavin | 5 mg |
| selenomethionine | 62.09 microgram |
| Equivalent: selenium | 25 microgram |
| thiamine hydrochloride | 63.54 mg |
| Equivalent: thiamine | 50 mg |
| Withania somnifera root Extract dry concentrate | 40 mg |
| Equivalent: Withania somnifera (Dry) | 500 mg |
| zinc amino acid chelate | 33.33 mg |
| Equivalent: zinc | 7.5 mg |

Other Ingredients (Excipients)

aluminium sodium silicate
aluminium starch octenylsuccinate
butylated hydroxytoluene
calcium hydrogen phosphate
Candelilla Wax
colloidal anhydrous silica
dl-alpha-tocopherol
ethylcellulose
Gelatin
hypromellose
magnesium stearate

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medium chain triglycerides
microcrystalline cellulose
purified water
silicon dioxide
sodium ascorbate
starch sodium octenyl succinate
sucrose
titanium dioxide
yellow beeswax

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