



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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
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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

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.

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

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.

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

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

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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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: folic 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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