



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	321474	MediHerb Vital Woman
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	8/08/2019	
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.

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 . MediHerb Vital Woman

Product Type	Effective Date
Single Medicine Product	3/11/2021

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Antioxidant/Reduce free radicals formed in the body in adolescents
- Antioxidant/Reduce free radicals formed in the body in females
- Antioxidant/Reduce free radicals formed in the body In older females
- Helps reduce/decrease free radical damage to body cells in females
- Helps reduce/decrease free radical damage to body cells In older females
- Helps reduce/decrease free radical damage to body cells
- Helps reduce/decrease free radical damage to body cells in adolescents
- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in females
- Maintain/support general health and wellbeing In older females
- Maintain/support general health and wellbeing in adolescents
- Maintain/support (state mineral) absorption in bones
- 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
- Maintain/support healthy immune system function in females
- Maintain/support healthy immune system function In older females
- Maintain/support healthy immune system function in adolescents
- Maintain/support healthy immune system function
- Helps enhance/promote/increase absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in adolescents
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in females
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body In older females
- Maintain/support (state vitamin/mineral) within normal range in females
- Maintain/support (state vitamin/mineral) within normal range

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Maintain/support (state vitamin/mineral) within normal range In older females
Maintain/support (state vitamin/mineral) within normal range in adolescents
Support healthy stress response in the body
Support healthy stress response in the body in females
Support healthy stress response in the body in adolescents
Support healthy stress response in the body In older females
Aid/assist/helps synthesis of neurotransmitters
Traditionally used in Western herbal medicine to decrease/reduce/relieve menstrual cycle irregularity/irregular periods
Decrease/reduce feelings of aggression/irritability associated with premenstrual tension
Decrease/reduce/relieve mood changes/mood swings associated with premenstrual tension
Decrease/reduce/relieve breast pain/tenderness associated with premenstrual tension
Decrease/reduce/relieve symptoms of premenstrual tension
Linked indication - Decrease/reduce/relieve abdominal bloating/distention
Traditionally used in Western herbal medicine to helps decrease/reduce/relieve night sweats associated with menopause
Traditionally used in Western herbal medicine to decrease/reduce/relieve hot flushes associated with menopause
Help to prevent neural tube defects such as spina bifida and/or anencephaly

Indication Requirements

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 serious immunological diseases.

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.

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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).

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: If symptoms persist, talk to your health professional.

Indication can only be used for medicines that contain folic acid as an active ingredient and the recommended daily dose of the medicine provides a minimum of 400 micrograms of folic acid. Product presentation referring to the prevention of neural tube defects must include at least one of the following label statements: when trying to conceive and during the first trimester of pregnancy, and/or when taken at least four weeks before conception and during the first trimester of pregnancy.

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

Product presentation must not imply or refer to gastro oesophageal reflux disease.

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.

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

If symptoms persist, seek the advice of a healthcare professional.

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.

Vitex agnus-castus may affect hormones and medicines such as oral contraceptives. Consult your health professional before use' (or words to that effect).

Not to be taken by children under 12 years old (or words to that effect).

For practitioner dispensing only.

Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida, seek specific medical advice (or words to that effect).

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



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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	100 mg
Asparagus racemosus root Extract dry concentrate	200 mg
Equivalent: Asparagus racemosus (Dry)	1200 mg
Biotin	150 microgram
borax	26.46 mg
Equivalent: boron	3 mg
calcium hydrogen phosphate dihydrate	258.18 mg
Equivalent: calcium	60 mg
Equivalent: phosphorus	46.48 mg
calcium pantothenate	50 mg
Equivalent: calcium	4.19 mg
Equivalent: pantothenic acid	45.81 mg
choline bitartrate	25 mg
chromic chloride hexahydrate	1.28 mg
Equivalent: chromium	250 microgram
colecalfiferol	.025 mg
cyanocobalamin	150 microgram
d-alpha-tocopheryl acid succinate	41.32 mg
Equivalent: d-alpha-tocopherol	50 IU
follic acid	500 microgram
inositol	25 mg
iron amino acid chelate	50 mg
Equivalent: iron	5 mg
magnesium amino acid chelate	150 mg
Equivalent: magnesium	30 mg
manganese amino acid chelate	20 mg
Equivalent: manganese	2 mg
mixed (low-alpha type) tocopherols concentrate	20.001 mg
molybdenum trioxide	150 microgram
Equivalent: molybdenum	100 microgram
nicotinamide	50 mg
phytomenadione	30 microgram
potassium iodide	391 microgram
Equivalent: iodine	299 microgram
Equivalent: potassium	92 microgram
pyridoxine hydrochloride	50 mg
Equivalent: pyridoxine	41.13 mg
retinol acetate	.3542 mg
Equivalent: vitamin A	.3003 mg
Reynoutria japonica root Extract dry concentrate standardised	20 mg
Equivalent: Reynoutria japonica (Dry)	2 g
riboflavin	30 mg

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selenomethionine	124.2 microgram
Equivalent: selenium	50 microgram
thiamine hydrochloride	50 mg
Vitex agnus-castus fruit Extract dry concentrate	25 mg
Equivalent: Vitex agnus-castus (Dry)	250 mg
zinc amino acid chelate	25 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

Acacia
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
crospovidone
dl-alpha-tocopherol
ethylcellulose
hypromellose
iron oxide red
macrogol 4000
macrogol 8000
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
polysorbate 80
polyvinyl alcohol
potable water
povidone
purified talc
silicon dioxide
Soya Oil
sucrose

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