



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	398816	BLACKMORES MULTIVITAMIN FOR TEEN GIRLS
ARTG entry for	Medicine Listed	
Sponsor	Blackmores Ltd	
Postal Address	217-221 Governor Road, Braeside, VIC, 3195 Australia	
ARTG Start Date	3/11/2022	
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 . BLACKMORES MULTIVITAMIN FOR TEEN GIRLS

Product Type	Single Medicine Product	Effective Date	3/11/2022
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Permitted Indications

- Maintain/support energy production
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Aids/assists healthy bone development/growth/building
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Support healthy stress response in the body
- Maintain/support cognitive function/mental function
- Maintain/support brain/central nervous system development
- Maintain/support skin health

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.
- 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 mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to neurological conditions or developmental delays.
- 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

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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 Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	40 mg
Biotin	25 microgram
calcium carbonate	17.5 mg
Equivalent: calcium	7 mg
calcium pantothenate	4.36 mg
Equivalent: pantothenic acid	4 mg
Equivalent: calcium	440 microgram
chromium picolinate	193 microgram
Equivalent: chromium	24 microgram
colecalfiferol	5 microgram
colloidal anhydrous silica	23.5 mg
Equivalent: silicon	11 mg
cyanocobalamin	.002 mg
d-alpha-tocopherol	8.72 mg
Dunaliella salina cell Extract soft concentrate standardised	75 mg
Equivalent: Dunaliella salina (Fresh)	75 mg
ferrous fumarate	15.7 mg
Equivalent: iron	5 mg
folic acid	200 microgram
heavy magnesium oxide	59.8 mg
Equivalent: magnesium	36 mg
natural fish oil	286 mg
Equivalent: eicosapentaenoic acid	51.5 mg
Equivalent: omega-3 marine triglycerides	85.8 mg
Equivalent: docosahexaenoic acid	34.3 mg
nicotinamide	14 mg
potassium iodide	197 microgram
Equivalent: iodine	150 microgram
pyridoxine hydrochloride	1.5 mg
Equivalent: pyridoxine	1.23 mg
riboflavin	1.1 mg
selenomethionine	125 microgram
Equivalent: selenium	50 microgram
thiamine nitrate	1.36 mg
Equivalent: thiamine	1.1 mg
zinc sulfate monohydrate	41.6 mg

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Equivalent: zinc

15 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
ethanol
Gelatin
glycerol
hydrogenated vegetable oil
iron oxide red
lecithin
mannitol
medium chain triglycerides
mixed (low-alpha type) tocopherols concentrate
purified water
Soya Oil
vegetable oil
yellow beeswax

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