



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	322408	BLACKMORES MULTIVITAMIN FOR MEN
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Blackmores Ltd	
<b>Postal Address</b>	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia	
<b>ARTG Start Date</b>	28/08/2019	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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.

The Ginkgo biloba leaf extract used in the manufacture of this medicine must comply with the requirement of Identification Test B of the monograph Powdered Ginkgo Extract in the United States Pharmacopeia 32 - National Formulary 27 (USP32-NF27) as in force or existing from time to time. This condition does not apply to powdered or dried leaf.

**Products**

**1 . BLACKMORES MULTIVITAMIN FOR MEN**

Product Type	Single Medicine Product	Effective Date	5/03/2021
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Helps convert (state food) into energy
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Maintain/support healthy blood circulation
- Traditionally used in Western herbal medicine to liver tonic/Enhance liver health
- Traditionally used in Western herbal medicine to maintain/support healthy liver function
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps post exercise recovery when dietary intake is inadequate in active individuals
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Support healthy stress response in the body
- Maintain/support cognitive function/mental function
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Maintain/support reproductive system health
- Maintain/support healthy sexual function
- Maintain/support sperm production

**Indication Requirements**

Product presentation must not imply or refer to serious immunological diseases.  
 If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased

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physical activity.

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

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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).

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**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**                      Tablet, film coated

**Route of Administration**        Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>100 mg</b>
<b>Biotin</b>	<b>50 microgram</b>
<b>calcium hydrogen phosphate</b>	<b>170 mg</b>
Equivalent: calcium	50 mg
<b>calcium pantothenate</b>	<b>70 mg</b>
Equivalent: pantothenic acid	64.13 mg
<b>cyanocobalamin</b>	<b>40 microgram</b>
<b>d-alpha-tocopheryl acid succinate</b>	<b>20.66 mg</b>
<b>folic acid</b>	<b>300 microgram</b>
<b>Ginkgo biloba leaf Extract dry concentrate standardised</b>	<b>10 mg</b>
Equivalent: Ginkgo biloba (Dry)	500 mg
<b>heavy magnesium oxide</b>	<b>63.09 mg</b>
Equivalent: magnesium	35 mg
<b>inositol</b>	<b>25 mg</b>
<b>manganese amino acid chelate</b>	<b>20 mg</b>
Equivalent: manganese	2 mg
<b>nicotinamide</b>	<b>30 mg</b>
<b>potassium iodide</b>	<b>65.4 microgram</b>
Equivalent: iodine	50 microgram
<b>pyridoxine hydrochloride</b>	<b>30 mg</b>
Equivalent: pyridoxine	24.68 mg
<b>riboflavin</b>	<b>15 mg</b>
<b>selenomethionine</b>	<b>64.6 microgram</b>
Equivalent: selenium	26 microgram
<b>Silybum marianum fruit Extract dry concentrate</b>	<b>57.14 mg</b>
Equivalent: Silybum marianum (Dry)	4 g

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<b>thiamine nitrate</b>	<b>30 mg</b>
Equivalent: thiamine	24.31 mg
<b>Tribulus terrestris fruit Extract dry concentrate</b>	<b>120 mg</b>
Equivalent: Tribulus terrestris (Dry)	6 g
<b>Turnera diffusa leaf Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Turnera diffusa (Dry)	1 g
<b>zinc amino acid chelate</b>	<b>75 mg</b>
Equivalent: zinc	15 mg

**Other Ingredients (Excipients)**

Carnauba Wax  
colloidal anhydrous silica  
croscarmellose sodium  
ethylcellulose  
hypromellose  
iron oxide black  
macrogol 400  
macrogol 8000  
magnesium stearate  
maltodextrin  
microcrystalline cellulose  
purified talc  
Spearmint oil  
titanium dioxide

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