



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	322408	BLACKMORES MULTIVITAMIN FOR MEN
ARTG entry for	Medicine Listed	
Sponsor	Blackmores Ltd	
Postal Address	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia	
ARTG Start Date	28/08/2019	
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.

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 infertility.
Product presentation must not imply or refer to serious immunological diseases.



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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.

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.

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.

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
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

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

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