



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	322666	BLACKMORES MULTIVITAMIN + IMMUNE
ARTG entry for	Medicine Listed	
Sponsor	Blackmores Ltd	
Postal Address	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia	
ARTG Start Date	4/09/2019	
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.

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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . BLACKMORES MULTIVITAMIN + IMMUNE

Product Type	Effective Date
Single Medicine Product	4/09/2019

Permitted Indications

- Maintain/support energy levels
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Maintain/support immune system health
- Maintain/support healthy immune system function
- 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
- Maintain/support nervous system health

Indication Requirements

- 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 serious immunological diseases.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- 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

Public Summary



Australian Government
Department of Health
 Therapeutic Goods Administration

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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.

Not for the treatment of iron deficiency conditions (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

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	180 mg
Biotin	25 microgram
calcium carbonate	100 mg
Equivalent: calcium	41.83 mg
calcium pantothenate	21.8 mg
Equivalent: pantothenic acid	20 mg
choline bitartrate	25 mg
colecalfiferol	.01 mg
cyanocobalamin	7 microgram
d-alpha-tocopheryl acid succinate	16.52 mg
Equivalent: d-alpha-tocopheryl acid succinate	20 IU
ferrous sulfate	16 mg
Equivalent: iron	5 mg
folic acid	200 microgram
heavy magnesium oxide	30.63 mg
Equivalent: magnesium	17.87 mg
inositol	25 mg
manganese sulfate monohydrate	6.16 mg
Equivalent: manganese	2 mg
nicotinamide	60 mg
potassium sulfate	55.75 mg
Equivalent: potassium	25 mg
pyridoxine hydrochloride	10 mg
Equivalent: pyridoxine	8.23 mg
retinol palmitate	2.78 mg
riboflavin	8.5 mg
thiamine nitrate	7.5 mg
Equivalent: thiamine	6.08 mg
zinc oxide	6.2 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

Public Summary



Australian Government

Department of Health
Therapeutic Goods Administration

calcium hydrogen phosphate
Carnauba Wax
chlorophyllin-copper complex
dl-alpha-tocopherol
ethylcellulose
Gelatin
glycerol
hydrogenated soya oil
hydrolysed gelatin
hypromellose
iron oxide yellow
magnesium stearate
maize starch
microcrystalline cellulose
silicon dioxide
sodium starch glycollate
sucrose
titanium dioxide

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary