



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

## Public Summary

<b>Summary for ARTG Entry:</b>	326027	BLACKMORES MULTIVITAMIN + ENERGY
<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>	8/11/2019	
<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.

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 + ENERGY

Product Type	Effective Date
Single Medicine Product	8/11/2019

### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Helps reduce/decrease free radical damage to body cells  
Maintain/support energy levels  
Maintain/support energy production  
Maintain/support physical endurance/capacity/stamina  
Relieve weariness/tiredness/fatigue/feeling of weakness  
Maintain/support general health and wellbeing  
Maintain/support bone health  
Maintain/support bone strength  
Maintain/support healthy thyroid gland function  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support muscle health  
Maintain/support muscle function  
Aid/assist/helps post exercise recovery  
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

### Indication Requirements



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

Label statement: If symptoms persist, talk to your health professional.

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

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.

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).

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 chronic fatigue syndrome.

Product presentation must not imply or refer to any thyroid related diseases.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Adults only.

The recommended dose of this medicine provides small amounts of caffeine

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.

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

**Additional Product information**

**Pack Size/Poison information**

**Pack Size** **Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form** Tablet, multilayer

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>50 mg</b>
<b>betacarotene</b>	<b>1 mg</b>
<b>Biotin</b>	<b>30 microgram</b>
<b>calcium folinate</b>	<b>555.56 microgram</b>
Equivalent: folic acid	400 microgram
<b>calcium hydrogen phosphate</b>	<b>253.88 mg</b>
Equivalent: calcium	74.8 mg
<b>calcium pantothenate</b>	<b>10.92 mg</b>
Equivalent: pantothenic acid	10 mg
<b>Camellia sinensis leaf Extract dry concentrate standardised</b>	<b>20 mg</b>
Equivalent: Camellia sinensis (Dry)	500 mg
<b>chromium picolinate</b>	<b>402.3 microgram</b>
Equivalent: chromium	50 microgram
<b>colecalfiferol</b>	<b>.005 mg</b>
<b>cyanocobalamin</b>	<b>35 microgram</b>
<b>Eleutherococcus senticosus root Extract dry concentrate</b>	<b>133.33 mg</b>
Equivalent: Eleutherococcus senticosus (Dry)	2 g
<b>inositol</b>	<b>30 mg</b>
<b>iron amino acid chelate</b>	<b>20 mg</b>

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Equivalent: iron	2 mg
<b>isoleucine</b>	<b>25 mg</b>
<b>leucine</b>	<b>50 mg</b>
<b>magnesium citrate</b>	<b>129.45 mg</b>
Equivalent: magnesium	20 mg
<b>magnesium phosphate pentahydrate</b>	<b>145.2 mg</b>
Equivalent: magnesium	30 mg
<b>nicotinamide</b>	<b>20 mg</b>
<b>potassium iodide</b>	<b>196.21 microgram</b>
Equivalent: iodine	150 microgram
<b>pyridoxal 5-phosphate monohydrate</b>	<b>3.91 mg</b>
Equivalent: pyridoxine	2.5 mg
<b>pyridoxine hydrochloride</b>	<b>27.35 mg</b>
Equivalent: pyridoxine	22.5 mg
<b>riboflavin</b>	<b>12 mg</b>
<b>riboflavin sodium phosphate</b>	<b>4.11 mg</b>
Equivalent: riboflavin	3 mg
<b>selenomethionine</b>	<b>173.87 microgram</b>
Equivalent: selenium	70 microgram
<b>thiamine hydrochloride</b>	<b>16.82 mg</b>
Equivalent: thiamine	15 mg
<b>valine</b>	<b>25 mg</b>
<b>zinc citrate dihydrate</b>	<b>43.61 mg</b>
Equivalent: zinc	14 mg

**Other Ingredients (Excipients)**

Acacia  
Carnauba Wax  
colloidal anhydrous silica  
Colour  
croscarmellose sodium  
d-alpha-tocopherol  
ethylcellulose  
fractionated coconut oil  
hypromellose  
liquid glucose  
magnesium stearate  
maltodextrin  
mannitol  
medium chain triglycerides  
microcrystalline cellulose  
polydextrose  
purified talc  
silicon dioxide  
sodium ascorbate  
triacetin

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