



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	153503	BLACKMORES EXECUTIVE B STRESS FORMULA
<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>	7/07/2008	
<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.

### Products

#### 1 . BLACKMORES EXECUTIVE B STRESS FORMULA

Product Type	Single Medicine Product	Effective Date	1/06/2023
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#### Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support energy levels
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Support healthy stress response in the body
- Maintain/support nervous system health
- Maintain/support nervous system function

#### Indication Requirements

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

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

- WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].
- If symptoms persist consult your healthcare practitioner (or words to that effect).
- 'Contains gluten (or words to that effect)'
- 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

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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	130 mg
Avena sativa seed Extract dry concentrate	25 mg
Equivalent: Avena sativa (Dry)	250 mg
Biotin	20 microgram
calcium ascorbate dihydrate	145 mg
Equivalent: ascorbic acid	119.77 mg
calcium pantothenate	75 mg
Equivalent: pantothenic acid	68.71 mg
calcium phosphate	100 mg
Equivalent: calcium	37 mg
choline bitartrate	25 mg
cyanocobalamin	30 microgram
d-alpha-tocopheryl acid succinate	41.3 mg
Equivalent: d-alpha-tocopheryl acid succinate	50 IU
folic acid	150 microgram
inositol	25 mg
lecithin	50 mg
magnesium phosphate pentahydrate	140 mg
Equivalent: magnesium	28.9 mg
monobasic potassium phosphate	117.3 mg
Equivalent: potassium	33.7 mg
nicotinamide	100 mg
Passiflora incarnata herb Extract dry concentrate	20 mg
Equivalent: Passiflora incarnata (Dry)	100 mg
pyridoxine hydrochloride	25 mg
Equivalent: pyridoxine	20.57 mg
riboflavin	10 mg
thiamine hydrochloride	75 mg

Other Ingredients (Excipients)

Carnauba Wax  
colloidal anhydrous silica  
croscarmellose sodium  
ethylcellulose  
hypromellose  
iron oxide black  
iron oxide red  
iron oxide yellow  
macrogol 400  
macrogol 8000  
magnesium stearate  
maltodextrin  
microcrystalline cellulose

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purified talc

silicon dioxide

tartaric acid

titanium dioxide

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