



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 153503 BLACKMORES EXECUTIVE B STRESS FORMULA

ARTG entry for Medicine Listed

Sponsor Blackmores Ltd

Postal Address PO Box 1725, WARRIEWOOD, NSW, 2102
Australia

ARTG Start Date 7/07/2008

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.

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 EXECUTIVE B STRESS FORMULA

Product Type	Single Medicine Product	Effective Date	16/03/2020
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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

'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.
If symptoms persist consult your healthcare practitioner (or words to that effect).

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	

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microcrystalline cellulose

purified talc

silicon dioxide

tartaric acid

titanium dioxide

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