



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 137809 BLACKMORES NUTRITIONAL COMPOUNDS M.L. 20

ARTG entry for Medicine Listed
Sponsor FIT-BioCeuticals Limited
Postal Address Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102
Australia
ARTG Start Date 24/04/2007
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.

Products

1 . BLACKMORES NUTRITIONAL COMPOUNDS M.L. 20

Product Type	Single Medicine Product	Effective Date	17/11/2020
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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
Anti-inflammatory/relieve inflammation
Maintain/support healthy muscle contraction function
Maintain/support muscle function
Maintain/support muscle relaxation
Maintain/support brain function
Maintain/support nervous system function
Maintain/support skin health

Indication Requirements

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.

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

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

Product presentation must not imply or refer to chronic fatigue syndrome.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Contains lactose (or words to that effect).

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Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, uncoated

Route of Administration Oral

Visual Identification

Active Ingredients

d-alpha-tocopheryl acid succinate	10 mg
dibasic potassium phosphate	33 mg
Equivalent: potassium	14.8 mg
lecithin	65 mg
magnesium phosphate pentahydrate	65 mg
Equivalent: magnesium	13.4 mg
Saccharomyces cerevisiae cell Dry	65 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
ethylcellulose
lactose monohydrate
magnesium stearate
microcrystalline cellulose
soy polysaccharide
tapioca starch

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