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

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).

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