



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	324885	BLACKMORES PROFESSIONAL NUTRITIONAL COMPOUNDS BIO-DISC
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	15/10/2019	
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 PROFESSIONAL NUTRITIONAL COMPOUNDS BIO-DISC

Product Type	Single Medicine Product	Effective Date	5/01/2021
--------------	-------------------------	----------------	-----------

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Maintain/support bone health
- Maintain/support healthy immune system function
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support skin health
- Maintain/support wound healing

Indication Requirements

- 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 mental illnesses, disorders or conditions.
- 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

- WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.
- The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.
- If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.
- Contains sulfites' (or words to this effect) if medicine contains two or more sulfite sources or 'Contains (insert the approved name of sulfites used)' (or words to this effect) if medicine contains one sulfite source.



Australian Government
Department of Health
 Therapeutic Goods Administration

Contains homoeopathic ingredients.

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.
 [Contains vitamin B6].

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	100 mg
bromelains	80 mg
calcium fluoride (Homeopathic)	950 mg
calcium phosphate	149.9 mg
Equivalent: calcium	58 mg
colloidal anhydrous silica	49.25 mg
Equivalent: silicon	23 mg
d-alpha-tocopheryl acid succinate	41.3 mg
magnesium phosphate pentahydrate	96.8 mg
Equivalent: magnesium	20 mg
manganese amino acid chelate	25 mg
Equivalent: manganese	2.5 mg
papain	50 mg
pyridoxine hydrochloride	50 mg
Equivalent: pyridoxine	41.13 mg
retinol palmitate	.278 mg
Equivalent: vitamin A	.15 mg
zinc amino acid chelate	25 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

- croscarmellose sodium**
- disodium edetate**
- dl-alpha-tocopherol**
- ethylcellulose**
- Gelatin**
- gellan gum**
- hypromellose**
- magnesium stearate**
- maize starch**
- maltodextrin**
- potable water**
- potassium acetate**
- sodium chloride**
- sodium metabisulfite**
- sucrose**

Public Summary



Australian Government

Department of Health
Therapeutic Goods Administration

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary