



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	91613	BLACKMORES PROFESSIONAL Z.B.M
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	4/11/2002	
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 Z.B.M

Product Type	Single Medicine Product	Effective Date	2/11/2022
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support healthy eyesight/vision
- Maintain/support healthy growth and development
- Helps maintain/support healthy blood sugar/glucose
- Maintain/support healthy immune system function
- Maintain/support healthy immune system function when dietary intake is inadequate
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Aid/assist/helps protein synthesis in the body
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters
- Maintains/support healthy foetal development
- Maintain/support healthy pregnancy
- Helps maintain/support testosterone formation/synthesis in males
- Help maintain/support healthy prostate function in males
- Maintain/support sperm health
- 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 lowering or raising blood sugar/glucose levels from outside of the normal healthy range.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to serious immunological diseases.
- Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
- If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
- Product presentation must not imply or refer to infertility.
- Product presentation must not imply or refer to serious genitourinary conditions like Benign Prostatic Hypertrophy, erectile dysfunction or hormone therapy.

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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 you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

WARNING: May be dangerous if taken in large amounts or for a long period. OR WARNING: Contains zinc which may be dangerous if taken in large amounts or for a long period (or words to that effect).

Additional Product information

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

magnesium phosphate pentahydrate	122 mg
Equivalent: magnesium	25.2 mg
manganese amino acid chelate	20 mg
Equivalent: manganese	2 mg
pyridoxine hydrochloride	50 mg
Equivalent: pyridoxine	41.1 mg
retinol acetate	.8625 mg
Equivalent: vitamin A	.75 mg
zinc amino acid chelate	125 mg
Equivalent: zinc	25 mg

Other Ingredients (Excipients)

- butylated hydroxytoluene
- Carnauba Wax
- croscarmellose sodium
- Gelatin
- hypromellose
- macrogol 400
- magnesium stearate
- maize starch
- microcrystalline cellulose
- purified talc
- silicon dioxide
- sucrose
- titanium dioxide



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