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.

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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 PROFESSIONAL Z.B.M

Product Type Single Medicine Product **Effective Date** 1/07/2019

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

Product presentation must not imply or refer to serious immunological diseases.

Product presentation must not imply or refer to serious genitourinary conditions like Benign Prostatic Hypertrophy, erectile dysfunction or hormone therapy.

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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

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 mental illnesses, disorders or conditions.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

Product presentation must not imply or refer to infertility.

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.

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**
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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