



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	91611	BLACKMORES BIO ZINC TABLET
ARTG entry for	Medicine Listed	
Sponsor	Blackmores Ltd	
Postal Address	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.

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 BIO ZINC TABLET

Product Type	Single Medicine Product	Effective Date	22/04/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support collagen formation
Maintain/support general health and wellbeing
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support (state vitamin/mineral) within normal range
Maintain/support reproductive system health
Maintain/support sperm health
Maintain/support sperm motility
Maintain/support skin health
Maintain/support skin integrity/structure
Maintain/support wound healing

Indication Requirements

Product presentation must not imply or refer to infertility.
Product presentation must not imply or refer to serious immunological diseases.
Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is inadequate OR [Vitamins/minerals/nutrients/dietary supplements] should not replace a balanced diet (or words to that effect).
Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

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.

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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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