Public Summary

Summary for ARTG Entry:	318345	BLACKMORES PROBIOTICS+ IMMUNE DEFENCE

ARTG entry for	Medicine Listed
Sponsor	Blackmores Ltd
Postal Address	PO Box 1725, WARRIEWOOD, NSW, 2102 Australia
ARTG Start Date	4/06/2019
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.

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 PROBIOTICS+ IMMUNE DEFENCE

Product Type	Single Medicine Product	**Effective Date**	20/01/2020

Permitted Indications

Maintain/support general health and wellbeing
Maintain/support intestinal health
Maintain/support healthy mucous linings of the digestive system
Maintain/support intestinal good/beneficial/friendly flora
Helps maintain/support good/beneficial/friendly gut flora during antibiotic use
Help restore good/beneficial/friendly gut flora after antibiotic use
Helps restore good/beneficial/friendly intestinal/gut/bowel flora
Nourish good/beneficial/friendly intestinal flora
Maintain/support gastrointestinal system health
Maintain/support immune system health
Maintain/support healthy immune system function
Maintain/support healthy gastrointestinal immune function
Decrease/reduce/relieve common cold duration
Decrease/reduce/relieve symptoms of common cold

Indication Requirements

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

Label statement: Adults only, OR Not to be used in children under 2 years of age without medical advice (or words to that effect).

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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

Warnings

Adults only. OR Not to be used in children under two years of age without medical advice (or words to that effect).

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

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	**200 mg**
Bifidobacterium animalis ssp lactis	**4.275 billion CFU**
Bifidobacterium bifidum	**225 million CFU**
Bifidobacterium lactis	**2 billion CFU**
inulin	**100 mg**
Lactobacillus acidophilus	**6.75 billion CFU**
Lactobacillus acidophilus	**6.75 billion CFU**
zinc citrate dihydrate	**16.2 mg**
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

colloidal anhydrous silica
dibasic potassium phosphate
disodium edetate
gellan gum
hypromellose
magnesium stearate
microcrystalline cellulose
monobasic potassium phosphate
potable water
potassium acetate
sucrose
trehalose dihydrate

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