



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	316500	ACTIVATED PROBIOTICS BIOME PRENATAL+
ARTG entry for	Medicine Listed	
Sponsor	Biome Australia Limited	
Postal Address	192/194 Johnston Street, Collingwood, VIC, 3066 Australia	
ARTG Start Date	15/04/2019	
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.

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 . ACTIVATED PROBIOTICS BIOME PRENATAL+

Product Type	Single Medicine Product	Effective Date	18/04/2020
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Permitted Indications

- Helps maintains/support healthy foetal CNS/brain development
- Enhance/promote healthy foetal development
- Maintain/support healthy pregnancy
- Helps enhance/promote maternal health
- Help to prevent neural tube defects such as spina bifida and/or anencephaly
- Helps enhance/promote preconception health

Indication Requirements

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.

Product presentation must not imply or refer to infertility.

Indication can only be used for medicines that contain folic acid as an active ingredient and the recommended daily dose of the medicine provides a minimum of 400 micrograms of folic acid. Product presentation referring to the prevention of neural tube defects must include at least one of the following label statements: when trying to conceive and during the first trimester of pregnancy, and/or when taken at least four weeks before conception and during the first trimester of pregnancy.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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



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Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Carton	Not recorded	Not recorded	Not recorded	Neither child resistant closure nor restricted flow insert	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

Bifidobacterium animalis ssp lactis	3 billion CFU
Bifidobacterium breve	5 billion CFU
colecalfiferol	10 microgram
cyanocobalamin	2.6 microgram
folic acid	.5 mg
Lactobacillus crispatus	1 billion CFU
Lactobacillus fermentum	1 billion CFU
Lactobacillus plantarum	5 billion CFU
Lactobacillus rhamnosus	5 billion CFU
potassium iodide	.2 mg
Equivalent: iodine	150 microgram

Other Ingredients (Excipients)

- glyceryl palmito-stearate
- hypromellose
- maltodextrin
- silicon dioxide
- titanium dioxide

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