



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

|                                |   |        |
|--------------------------------|---|--------|
| <b>Summary for ARTG Entry:</b> | 374337  | Synbac |
| <b>ARTG entry for</b>          | Medicine Listed   |        |
| <b>Sponsor</b>                 | Nutrition Care Pharmaceuticals Pty Ltd                        |        |
| <b>Postal Address</b>          | 25-31 Keysborough Avenue, Keysborough, VIC, 3173<br>Australia |        |
| <b>ARTG Start Date</b>         | 7/09/2021   |        |
| <b>Product Category</b>        | Medicine  |        |
| <b>Status</b>                  | Active  |        |
| <b>Approval Area</b>           | 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 . Synbac**

| Product Type | Single Medicine Product | Effective Date | 7/09/2021 |
|--------------|-------------------------|----------------|-----------|
|--------------|-------------------------|----------------|-----------|

**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Maintain/support general health and wellbeing
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- Maintain/support intestinal health
- Maintain/support intestinal good/beneficial/friendly flora
- Maintain/support gastrointestinal system health
- Maintain/support gastrointestinal mucosal membrane health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support healthy gastrointestinal immune function
- Aid/assist/helps protein synthesis in the body
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support preconception health
- Maintain/support preconception health in healthy females
- Maintain/support sperm health in healthy males
- Maintain/support sperm production in healthy males

**Indication Requirements**

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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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).

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

Product presentation must not imply or refer to infertility.

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

If product is indicated for supplementation, 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).

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

No Warnings included on Record

**Additional Product information**

**Pack Size/Poison information**

| Pack Size | Poison Schedule |
|-----------|-----------------|
|-----------|-----------------|

**Components**

**1 . Formulation 1**

**Dosage Form** Powder, oral  
**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

|   |                          |
|---|--------------------------|
| <b>Aloe vera leaf Juice powder</b>        | <b>10 mg/g</b>           |
| Equivalent: Aloe vera ( )                 | 2 g/g                    |
| <b>ascorbic acid</b>                      | <b>10 mg/g</b>           |
| <b>Bifidobacterium longum</b>             | <b>200 million CFU/g</b> |
| <b>fructooligosaccharides</b>             | <b>150 mg/g</b>          |
| <b>Lactobacillus acidophilus</b>          | <b>1.4 billion CFU/g</b> |
| <b>Lactobacillus plantarum</b>            | <b>1.4 billion CFU/g</b> |
| <b>Ulmus rubra stem bark inner Powder</b> | <b>100 mg/g</b>          |
| <b>zinc amino acid chelate</b>            | <b>10 mg/g</b>           |
| Equivalent: zinc                          | 2 mg/g                   |

**Other Ingredients (Excipients)**

**maltodextrin**  
**microcrystalline cellulose**  
**xylitol**

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