



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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|--------------------------------|---|-----------------------|
| Summary for ARTG Entry: | 421716 | Daily Probiotics Gold |
| ARTG entry for | Medicine Listed | |
| Sponsor | Nutrition Care Pharmaceuticals Pty Ltd | |
| Postal Address | 25-31 Keysborough Avenue, Keysborough, VIC, 3173 Australia | |
| ARTG Start Date | 13/09/2023 | |
| 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.

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 . Daily Probiotics Gold

| | | | |
|---------------------|-------------------------|-----------------------|------------|
| Product Type | Single Medicine Product | Effective Date | 13/09/2023 |
|---------------------|-------------------------|-----------------------|------------|

Permitted Indications

Maintain/support general health and wellbeing
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

Indication Requirements

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

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 | Capsule, hard |
|--------------------|---------------|

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Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|--|-------------------|
| Bifidobacterium bifidum | 75 million CFU |
| Bifidobacterium breve | 230 million CFU |
| Bifidobacterium lactis | 10 billion CFU |
| Bifidobacterium longum | 75 million CFU |
| Lactobacillus acidophilus | 12.5 billion CFU |
| Lactobacillus brevis | 150 million CFU |
| Lactobacillus casei | 5.515 billion CFU |
| Lactobacillus delbrueckii ssp bulgaricus | 35 million CFU |
| Lactobacillus fermentum | 75 million CFU |
| Lactobacillus gasseri | 150 million CFU |
| Lactobacillus paracasei | 305 million CFU |
| Lactobacillus plantarum | 300 million CFU |
| Lactobacillus reuteri | 20 million CFU |
| Lactobacillus rhamnosus | 265 million CFU |
| Lactobacillus salivarius ssp salivarius | 10 billion CFU |
| Streptococcus thermophilus | 305 million CFU |

Other Ingredients (Excipients)

colloidal anhydrous silica
disodium edetate
gellan gum
hypromellose
magnesium stearate
microcrystalline cellulose
potable water
potassium acetate

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