



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	347700	Perdays Pregnancy Probiotic 360° & Vitamin D
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	PERDAY'S HEALTH FUNCTIONAL FOOD (AU) PTY LTD	
<b>Postal Address</b>	Suite 505 Level 5 815 Pacific Highway, Chatswood, NSW, 2067 Australia	
<b>ARTG Start Date</b>	9/11/2020	
<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 . Perdays Pregnancy Probiotic 360° & Vitamin D

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	27/06/2022
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#### Permitted Indications

Maintain/support general health and wellbeing

Helps maintain/support healthy blood sugar/glucose

Support healthy emotional/mood balance

Maintain/support vaginal healthy flora/microflora

Helps reduce occurrence of symptoms of eczema/dermatitis in healthy children under 2 years of age

#### Indication Requirements

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

Label statement: If symptoms persist, talk to your health professional.

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

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

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

#### Additional Product information

#### Pack Size/Poison information

<b>Pack Size</b>	<b>Poison Schedule</b>
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#### Components

##### 1 . Formulation 1

<b>Dosage Form</b>	Capsule, hard
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<b>Route of Administration</b>	Oral
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**Visual Identification**

**Active Ingredients**

<b>Bifidobacterium animalis ssp lactis</b>	<b>100 million CFU</b>
<b>Bifidobacterium breve</b>	<b>100 million CFU</b>
<b>Bifidobacterium infantis</b>	<b>100 million CFU</b>
<b>Bifidobacterium lactis</b>	<b>100 million CFU</b>
<b>Bifidobacterium longum</b>	<b>100 million CFU</b>
<b>colecalfiferol</b>	<b>.025 mg</b>
<b>fructooligosaccharides</b>	<b>10 mg</b>
<b>Lactobacillus acidophilus</b>	<b>9 billion CFU</b>
<b>Lactobacillus delbrueckii ssp bulgaricus</b>	<b>100 million CFU</b>
<b>Lactobacillus paracasei</b>	<b>100 million CFU</b>
<b>Lactobacillus plantarum</b>	<b>100 million CFU</b>
<b>Lactobacillus reuteri</b>	<b>100 million CFU</b>
<b>Lactobacillus rhamnosus</b>	<b>6 billion CFU</b>
<b>Lactobacillus salivarius ssp salivarius</b>	<b>100 million CFU</b>

**Other Ingredients (Excipients)**

carrageenan  
colloidal anhydrous silica  
dl-alpha-tocopherol  
hydrated silica  
hypromellose phthalate  
hypromellose  
magnesium stearate  
maltodextrin  
medium chain triglycerides  
microcrystalline cellulose  
potassium acetate  
purified water  
titanium dioxide  
trehalose dihydrate  
vegetable oil

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