



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

## Public Summary

<b>Summary for ARTG Entry:</b>	374316	Perdays Pregnancy Calcium & 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>	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 . Perdays Pregnancy Calcium & Vitamin D

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	24/09/2021
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### Permitted Indications

- Maintain/support general health and wellbeing
- Maintain/support healthy teeth
- Maintain/support teeth mineralisation in breast fed healthy infants
- Maintain/support bone health
- Help maintain/support bone mineralisation in breast fed healthy infants
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support healthy pregnancy

### Indication Requirements

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

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

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).

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

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**Pack Size/Poison information**

**Pack Size**

**Poison Schedule**

**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>calcium citrate tetrahydrate</b>	<b>793.65 mg</b>
Equivalent: calcium	166.67 mg
<b>colecalfiferol</b>	<b>.0016 mg</b>

**Other Ingredients (Excipients)**

Carnauba Wax  
colloidal anhydrous silica  
croscarmellose sodium  
dl-alpha-tocopherol  
hydrogenated soya oil  
hydrolysed gelatin  
hypromellose  
macrogol 400  
magnesium stearate  
maize starch  
microcrystalline cellulose  
povidone  
silicon dioxide  
sucrose  
titanium dioxide

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