



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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|--------------------------------|--|------------------------------------|
| Summary for ARTG Entry: | 374315 | Perdays Pregnancy Iron & Vitamin C |
| ARTG entry for | Medicine Listed | |
| Sponsor | PERDAY'S HEALTH FUNCTIONAL FOOD (AU) PTY LTD | |
| Postal Address | Suite 505 Level 5 815 Pacific Highway, Chatswood, NSW, 2067 Australia | |
| ARTG Start Date | 7/09/2021 | |
| 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 . Perdays Pregnancy Iron & Vitamin C

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

Permitted Indications

Maintain/support energy levels when dietary intake is inadequate
Maintain/support red blood cell health when dietary intake is inadequate
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Maintain/support healthy pregnancy

Indication Requirements

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 chronic fatigue syndrome.
Product presentation must not imply or refer to serious cardiovascular conditions.
Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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 | Tablet, film coated |
|--------------------|---------------------|

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Route of Administration Oral

Visual Identification

Active Ingredients

| | |
|---------------------|--------|
| ascorbic acid | 125 mg |
| iron (II) glycinate | 120 mg |
| Equivalent: iron | 24 mg |

Other Ingredients (Excipients)

brilliant scarlet 4R aluminium lake
calcium hydrogen phosphate dihydrate
citric acid
colloidal anhydrous silica
croscarmellose sodium
crospovidone
hypromellose
macrogol 3350
magnesium stearate
maltodextrin
microcrystalline cellulose
polyvinyl alcohol
povidone
purified talc
sunset yellow FCF aluminium lake
tartaric acid
titanium dioxide

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