



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	346423	Perdays Pregnancy Key Essentials & DHA
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	22/10/2020	
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 Key Essentials & DHA

Product Type	Single Medicine Product	Effective Date	22/10/2020
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Permitted Indications

Helps enhance/promote healthy growth and development
Helps enhance/promote general health and wellbeing
Maintain/support brain/central nervous system development
Support healthy emotional/mood balance
Helps maintains/support healthy foetal CNS/brain development
Enhance/promote healthy foetal development
Maintains/support healthy foetal development
Maintain/support healthy pregnancy
Maintain/support maternal health
Help to prevent neural tube defects such as spina bifida and/or anencephaly
Maintain/support preconception health

Indication Requirements

Product presentation must not imply or refer to neurological conditions or developmental delays.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
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.
Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

Indication can only be used for medicines that contain folic acid as an active ingredient and the recommended daily dose of the medicine provides a minimum of 400 micrograms of folic acid. Product presentation referring to the prevention of neural tube defects must include at least one of the following label statements: when trying to conceive and during the first trimester of pregnancy, and/or when taken at least four weeks before conception and during the first trimester of pregnancy.

Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet. This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

Additional Product information

Pack Size/Poison information

Pack Size **Poison Schedule**

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

betacarotene	800 microgram
calcium folinate	273 microgram
Equivalent: folic acid	250 microgram
colecalfiferol	.0062 mg
cyanocobalamin	1.3 microgram
docosahexaenoic acid (DHA)-rich oil derived from microalgae Schizochytrium sp.	250 mg
Equivalent: docosahexaenoic acid	100 mg
ferrous sulfate	15.4226 mg
Equivalent: iron	5 mg
nicotinamide	9 mg
potassium iodide	98.1 microgram
Equivalent: iodine	75 microgram
pyridoxine hydrochloride	1.1588 mg
Equivalent: pyridoxine	950 microgram
riboflavin	700 microgram
selenomethionine	83 microgram
Equivalent: selenium	32.5 microgram
thiamine nitrate	863.5 microgram
Equivalent: thiamine	700 microgram
zinc citrate dihydrate	17.1334 mg
Equivalent: zinc	5.5 mg

Other Ingredients (Excipients)

Acacia
ascorbic acid
carrageenan
colloidal anhydrous silica
d-alpha-tocopherol
d-alpha-tocopheryl acetate
hypromellose
iron oxide red
magnesium stearate
maize starch
maltodextrin
medium chain triglycerides
microcrystalline cellulose
potassium acetate

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purified water
silicon dioxide
sodium ascorbate
Soya Oil
titanium dioxide

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