



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	378237 Iron & Brain Support
ARTG entry for	Medicine Listed
Sponsor	NRC Nutrition Pty Ltd
Postal Address	PO Box 1248, Coolumb Beach, QLD, 4573 Australia
ARTG Start Date	18/11/2021
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 . Iron & Brain Support

Product Type	Single Medicine Product	Effective Date	18/11/2021
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Permitted Indications

Maintain/support energy levels
Maintain/support red blood cell health
Maintain/support blood health
Helps maintain/support haemoglobin formation/synthesis
Helps decrease/reduce homocysteine levels
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Maintain/support brain function
Maintain/support brain health
Maintain/support brain/central nervous system development
Helps maintains/support healthy foetal CNS/brain development
Maintains/support healthy foetal development
Maintain/support healthy pregnancy
Maintain/support preconception health
Helps prepare the body for pregnancy

Indication Requirements

Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
Product presentation must not imply or refer to neurological conditions or developmental delays.
Product presentation must not imply or refer to serious cardiovascular conditions.
If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
Product presentation must not imply or refer to chronic fatigue syndrome.
Product presentation must not imply or refer to mental illnesses, disorders or conditions.
Product presentation must not imply or refer to infertility.

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



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Specific Indications

No Specific Indications included on Record

Warnings

Not for the treatment of iron deficiency conditions (or words to that effect).

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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

calcium folinate	330 microgram
Equivalent: folic acid	300 microgram
choline bitartrate	607.78 mg
Equivalent: choline	250 mg
hydroxocobalamin	50 microgram
iron (II) glycinate	88.8 mg
Equivalent: iron	24 mg
magnesium ascorbate monohydrate	56.04 mg
Equivalent: magnesium	3.47 mg
Equivalent: ascorbic acid	50 mg

Other Ingredients (Excipients)

Acacia
citric acid
colloidal anhydrous silica
edetic acid
gellan gum
hypromellose
leucine
maltodextrin
microcrystalline cellulose
Oryza sativa
potable water
potassium acetate
silicon dioxide
Sunflower Oil

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