



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	367671	Iron & Brain Support
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	NRC Nutrition Pty Ltd	
<b>Postal Address</b>	PO Box 380, Peregian Beach, QLD, 4573 Australia	
<b>ARTG Start Date</b>	1/06/2021	
<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 . Iron & Brain Support

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	1/06/2021
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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

- 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.
- Product presentation must not imply or refer to chronic fatigue syndrome.
- 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 mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- 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 neurological conditions or developmental delays.

#### 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**

<b>calcium folinate</b>	<b>325.52 microgram</b>
Equivalent: folic acid	300 microgram
<b>choline bitartrate</b>	<b>607.82 mg</b>
Equivalent: choline	250 mg
<b>hydroxocobalamin</b>	<b>50 microgram</b>
<b>iron (II) glycinate</b>	<b>120 mg</b>
Equivalent: iron	24 mg
<b>magnesium ascorbate monohydrate</b>	<b>56.04 mg</b>
Equivalent: ascorbic acid	50 mg
Equivalent: magnesium	3.47 mg

**Other Ingredients (Excipients)**

colloidal anhydrous silica  
edetic acid  
gellan gum  
hypromellose  
leucine  
microcrystalline cellulose  
potable water  
potassium acetate

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