



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

## Public Summary

<b>Summary for ARTG Entry:</b>	386947	Iron +
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	JSHealth Vitamins Pty Ltd	
<b>Postal Address</b>	31 Knox Street, Double Bay, Sydney, NSW, 2028 Australia	
<b>ARTG Start Date</b>	11/04/2022	
<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 +

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	11/04/2022
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### Permitted Indications

Antioxidant/Reduce free radicals formed in the body  
Maintain/support energy levels  
Maintain/support energy production  
Maintain/support vitality  
Relieve weariness/tiredness/fatigue/feeling of weakness when dietary intake is inadequate  
Maintain/support general health and wellbeing  
Aid/assist healthy red blood cell production  
Maintain/support blood health  
Helps maintain/support transport of oxygen in the body  
Aid/assist/helps oxygen transport to body tissues  
Maintain/support immune system health  
Maintain/support healthy immune system function  
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)  
Maintain/support (state vitamin/mineral/nutrient) levels in the body  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in healthy females  
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency  
Maintain/support cognitive function/mental function  
Aid/assist/helps synthesis of neurotransmitters  
Maintain/support nervous system health  
Maintain/support nervous system function

### Indication Requirements

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to heart disease.

Product presentation must not imply or refer to serious immunological diseases.

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased physical activity.

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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 serious cardiovascular conditions.

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

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).

Label statement: If symptoms persist, talk to your health professional.

**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
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**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>calcium ascorbate dihydrate</b>	<b>60.52 mg</b>
Equivalent: ascorbic acid	50 mg
<b>calcium folinate</b>	<b>110 microgram</b>
Equivalent: folic acid	100 microgram
<b>iron amino acid chelate</b>	<b>120 mg</b>
Equivalent: iron	24 mg
<b>mecobalamin (co-methylcobalamin)</b>	<b>25 microgram</b>
<b>pyridoxine hydrochloride</b>	<b>6.08 mg</b>
Equivalent: pyridoxine	5 mg
<b>riboflavin</b>	<b>10 mg</b>
<b>thiamine hydrochloride</b>	<b>10 mg</b>

**Other Ingredients (Excipients)**

- calcium hydrogen phosphate dihydrate
- Carnauba Wax
- colloidal anhydrous silica
- croscarmellose sodium
- crospovidone
- hypromellose
- iron oxide black
- iron oxide red
- macrogol 400
- magnesium stearate
- microcrystalline cellulose
- povidone

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