



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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

Product Type	Single Medicine Product	Effective Date	5/01/2023
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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

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).

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).

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

Product presentation must not imply or refer to serious cardiovascular conditions.



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

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

Product presentation must not imply or refer to heart disease.

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.

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

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

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

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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