



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	345762	IRON PLUS
ARTG entry for	Medicine Listed	
Sponsor	Interclinical Laboratories Pty Ltd	
Postal Address	PO Box 6474, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	12/10/2020	
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 . IRON PLUS

Product Type	Single Medicine Product	Effective Date	12/10/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Maintain/support collagen formation
Maintain/support energy levels
Maintain/support energy production
Maintain/support healthy eye function
Maintain/support eye health
Maintain/support body mucous membrane health
Maintain/support general health and wellbeing
Maintain/support hair growth
Maintain/support hair health
Maintain/support healthy teeth
Aid/assist nail growth
Maintain/support nail health/strength/thickness
Maintain/support connective tissue health
Aid/assist/helps connective tissue production/formation
Maintain/support healthy body tissues
Maintain/support bone health
Aid/assist healthy red blood cell production
Maintain/support red blood cell health
Maintain/support blood health
Helps maintain/support transport of oxygen in the body
Aid/assist/helps oxygen transport to body tissues
Helps maintain/support haemoglobin formation/synthesis
Maintain/support blood capillary health
Maintain/support blood vessel health
Maintain/support immune system health
Maintain/support healthy immune system function

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Aid/assist/helps protein synthesis in the body
 Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
 Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
 Aid/assist/helps synthesis of neurotransmitters
 Maintain/support nervous system health
 Maintain/support nervous system function
 Maintains/support healthy foetal development
 Maintain/support healthy pregnancy
 Maintain/support preconception health in healthy females
 Maintain/support skin health
 Maintain/support wound healing

Indication Requirements

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.

Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.

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 mental illnesses, disorders or conditions.

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

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

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

Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis. Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.

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

Product presentation must not imply or refer to infertility.

Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.

Product presentation must not imply or refer to heart disease.

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

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

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Child resistant closure	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral

Visual Identification

Active Ingredients

ascorbic acid	50 mg
iron amino acid chelate	100 mg

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Equivalent: iron	20 mg
levomefolate calcium	487.2767 microgram
Equivalent: levomefolic acid	450 microgram
riboflavin	2 mg

Other Ingredients (Excipients)

citric acid
colloidal anhydrous silica
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
purified water

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