



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	297027	MediHerb Fe-Max Iron Tonic
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	30/11/2017	
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 . MediHerb Fe-Max Iron Tonic

Product Type	Single Medicine Product	Effective Date	24/01/2022
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Permitted Indications

- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Traditionally used in Western herbal medicine to body tonic
- Maintain/support general health and wellbeing in adolescents
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing
- Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in teenagers
- 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
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in adolescents
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in teenagers
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral) within normal range
- Maintain/support (state vitamin/mineral) within normal range in adolescents
- Maintain/support (state vitamin/mineral) within normal range in teenagers

Indication Requirements

- Product presentation must not imply or refer to heart disease.
- 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 Ayurvedic terminology is used on medicine label, label statement: Talk to a Ayurvedic practitioner/health professional if you are unsure if this medicine is right for you.
- 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 serious cardiovascular conditions.

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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

If symptoms persist, seek the advice of a healthcare professional.

If symptoms persist consult your healthcare practitioner (or words to that effect).

Contains sorbates' (or word to this effect) if medicine contains two or more sorbate sources OR 'Contains [insert the approved name of sorbate source used]' (or words to this effect) if medicine contains one sorbate source.

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

Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

Codonopsis pilosula root Extract liquid	200 microlitre/mL
Equivalent: Codonopsis pilosula (Dry)	100 mg/mL
cyanocobalamin	.3 microgram/mL
Glycyrrhiza glabra root Extract dry concentrate	25 mg/mL
Equivalent: Glycyrrhiza glabra (Dry)	100 mg/mL
iron amino acid chelate	5 mg/mL
Equivalent: iron	1 mg/mL
pyridoxine hydrochloride	500 microgram/mL
Equivalent: pyridoxine	411 microgram/mL
riboflavin	500 microgram/mL
Urtica dioica leaf Extract liquid	200 microlitre/mL
Equivalent: Urtica dioica (Dry)	100 mg/mL
Withania somnifera root Extract dry concentrate	20 mg/mL
Equivalent: Withania somnifera (Dry)	240 mg/mL
Zingiber officinale rhizome Extract liquid	20 microlitre/mL
Equivalent: Zingiber officinale (Dry)	10 mg/mL

Other Ingredients (Excipients)

Apple

ascorbic acid

beetroot

citric acid monohydrate

Flavour

glycerol

Grape

Lemon

maltodextrin



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Pear

potable water

potassium sorbate

purified water

silicon dioxide

sodium citrate dihydrate

Stevia rebaudiana

thiamine hydrochloride

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