



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	299646	Mediherb Fe-Max Tablet
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	14/02/2018	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 Tablet

Product Type	Single Medicine Product	Effective Date	28/03/2019
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Permitted Indications

- Traditionally used in Ayurvedic medicine to rasayan/rejuvenative tonic
- Helps convert (state food) into energy
- Traditionally used in Ayurvedic medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing
- 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
- Aid/assist/helps glucose/sugar/carbohydrate metabolism
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in vegetarians
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in athletes
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in active individuals
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in elderly individuals
- Maintain/support (state vitamin/mineral/nutrient) levels in the body In older males
- Maintain/support (state vitamin/mineral/nutrient) levels in the body In older females
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women

Public Summary



Australian Government
Department of Health
 Therapeutic Goods Administration

- Maintain/support (state vitamin/mineral/nutrient) levels in the body in healthy females
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in teenagers
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in adolescents
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support (state vitamin/mineral) within normal range
- Maintain/support (state vitamin/mineral) within normal range in healthy teenagers
- Maintain/support (state vitamin/mineral) within normal range in healthy females
- Maintain/support (state vitamin/mineral) within normal range in breastfeeding women
- Maintain/support (state vitamin/mineral) within normal range in vegetarians
- Maintain/support (state vitamin/mineral) within normal range In older males
- Maintain/support (state vitamin/mineral) within normal range in healthy elderly individuals
- Maintain/support (state vitamin/mineral) within normal range in athletes
- Maintain/support (state vitamin/mineral) within normal range in active individuals
- Maintain/support (state vitamin/mineral) within normal range in vegans
- Maintain/support (state vitamin/mineral) within normal range in healthy adolescents
- Maintain/support (state vitamin/mineral) within normal range In older females

Indication Requirements

If product is indicated for supplementation, Label statement: 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.

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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.

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

Product presentation must not imply or refer to lowering or raising blood sugar/glucose levels from outside of the normal healthy range.

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.

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 consult your healthcare practitioner (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.

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

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	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

ascorbic acid	120 mg
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Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Codonopsis pilosula	83.33 mg
Equivalent: Codonopsis pilosula	500 mg
iron amino acid chelate	60 mg
Equivalent: iron	12 mg
levomefolate calcium	108 microgram
Equivalent: levomefolic acid	100 microgram
mecobalamin (co-methylcobalamin)	250 microgram
pyridoxal 5-phosphate monohydrate	7.84 mg
Equivalent: pyridoxine	5 mg
riboflavin sodium phosphate	6.91 mg
Equivalent: riboflavin	5 mg
Withania somnifera	150 mg
Equivalent: Withania somnifera	1.8 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
croscarmellose sodium
hypromellose
iron oxide black
iron oxide red
iron oxide yellow
macrogol 400
magnesium stearate
maltodextrin
microcrystalline cellulose
silicon dioxide
sodium starch glycollate
titanium dioxide

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Public Summary