



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	375462	Organic Iron MAX
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	29/09/2021	
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 . Organic Iron MAX

Product Type	Single Medicine Product	Effective Date	29/09/2021
---------------------	-------------------------	-----------------------	------------

Permitted Indications

- Maintain/support energy production
- Maintain/support energy production in children
- Maintain/support general health and wellbeing in children
- Maintain/support general health and wellbeing
- Aid/assist healthy red blood cell production
- Aid/assist healthy red blood cell production in children
- Maintain/support red blood cell health
- Maintain/support red blood cell health in children
- Maintain/support blood health in children
- 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 immune system health
- Maintain/support healthy immune system function
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient) in children
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in children
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support healthy pregnancy

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

Public Summary



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

physical activity.

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

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

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.

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 heart disease.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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 Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Arthrospira maxima	100 mg
calcium ascorbate dihydrate	304.32 mg
Equivalent: ascorbic acid	250 mg
iron amino acid chelate	120 mg
Equivalent: iron	24 mg
levomefolate glucosamine	376 microgram
Equivalent: levomefolic acid	200 microgram
mecobalamin (co-methylcobalamin)	200 microgram
pyridoxine hydrochloride	12.16 mg
Equivalent: pyridoxine	10 mg
riboflavin	10 mg
Spinacia oleracea leaf Powder	25 mg
thiamine hydrochloride	12.71 mg
Equivalent: thiamine	10 mg

Other Ingredients (Excipients)

citric acid
 colloidal anhydrous silica
 hypromellose
 magnesium stearate
 maltodextrin

Public Summary



Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

microcrystalline cellulose

purified water

silicon dioxide

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary