



**Australian Government**  
**Department of Health and Aged Care**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	372450	ORGANIC Iron COMPLETE
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Bio-Practica Pty Ltd	
<b>Postal Address</b>	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia	
<b>ARTG Start Date</b>	9/08/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 COMPLETE**

Product Type	Single Medicine Product	Effective Date	9/08/2021
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Maintain/support energy levels
- Helps convert (state food) into energy
- Maintain/support body metabolism/metabolic rate
- Maintain/support energy production
- Maintain/support heat/energy production/thermogenesis
- Maintain/support general health and wellbeing
- 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 healthy thyroid gland function
- Maintain/support healthy thyroid hormones
- Maintain/support thyroid gland health
- Aid/assist thyroid hormone production
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Aid/assist/helps protein synthesis in the body

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- 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)
- Maintain/support cognitive function/mental function
- Maintain/support nerve conduction
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support female reproductive system health
- Maintain/support preconception health in healthy males
- Maintain/support preconception health in healthy females
- Maintain/support reproductive system health in males
- Maintain/support healthy reproductive hormones
- Maintain/support sperm health in healthy males
- Maintain/support sperm production in healthy males
- Maintain/support testosterone level
- Maintain/support skin health
- Maintain/support skin integrity/structure
- Maintain/support skin regeneration
- Maintain/support wound healing

**Indication Requirements**

- Product presentation must not imply or refer to any thyroid related diseases.
- Product presentation must not imply or refer to mental illnesses, disorders or conditions.
- Product presentation must not imply or refer to infertility.
- 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 immunological diseases.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to heart disease.
- Product presentation must not imply or refer to hormone imbalances.
- If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
- 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).
- 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 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 chronic fatigue syndrome.

**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**

**Pack Size/Poison information**

<b>Pack Size</b>	<b>Poison Schedule</b>
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**Components**

- 1 . Formulation 1



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**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>calcium ascorbate dihydrate</b>	<b>182.59 mg</b>
Equivalent: ascorbic acid	150 mg
<b>calcium folinate</b>	<b>217 microgram</b>
Equivalent: folic acid	200 microgram
<b>hydroxocobalamin</b>	<b>500 microgram</b>
<b>iron (II) glycinate</b>	<b>87.7 mg</b>
Equivalent: iron	24 mg
<b>potassium iodide</b>	<b>130.8 microgram</b>
Equivalent: iodine	100 microgram
<b>pyridoxal 5-phosphate monohydrate</b>	<b>7.84 mg</b>
Equivalent: pyridoxine	5 mg
<b>riboflavin sodium phosphate</b>	<b>19.74 mg</b>
Equivalent: riboflavin	15 mg
<b>Rosa canina fruit Extract dry concentrate</b>	<b>16.67 mg</b>
Equivalent: Rosa canina (Dry)	100.02 mg
<b>zinc citrate dihydrate</b>	<b>46.73 mg</b>
Equivalent: zinc	15 mg

**Other Ingredients (Excipients)**

citric acid  
colloidal anhydrous silica  
hypromellose  
maltodextrin  
microcrystalline cellulose  
silicon dioxide  
stearic acid

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