



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

**Public Summary**

<b>Summary for ARTG Entry:</b>	266925	Thompson's Organic Iron
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	8/01/2016	
<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 . Thompson's Organic Iron**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	12/10/2022
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**Permitted Indications**

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

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Maintain/support (state vitamin/mineral) within normal range in elderly individuals

**Indication Requirements**

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

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

**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

<b>Dosage Form</b>	Tablet, film coated
<b>Route of Administration</b>	Oral

**Visual Identification**

**Active Ingredients**

ascorbic acid	30 mg
cyanocobalamin	2 microgram
folic acid	100 microgram
iron amino acid chelate	120 mg
Equivalent: iron	24 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate  
 citric acid monohydrate  
 colloidal anhydrous silica  
 croscarmellose sodium  
 hypromellose  
 iron oxide black  
 iron oxide red  
 iron oxide yellow  
 macrogol 400  
 magnesium stearate  
 maltodextrin  
 microcrystalline cellulose  
 potable water  
 sodium citrate dihydrate  
 titanium dioxide

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