



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	298872	ETHICAL NUTRIENTS MEGA IRON
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	23/01/2018	
<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 . ETHICAL NUTRIENTS MEGA IRON

Product Type	Effective Date
Single Medicine Product	18/12/2020

### Permitted Indications

- Maintain/support energy levels
- Maintain/support energy production
- Relieve weariness/tiredness/fatigue/feeling of weakness in healthy adults
- Relieve weariness/tiredness/fatigue/feeling of weakness when dietary intake is inadequate
- Maintain/support general health and wellbeing
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood health
- Maintain/support immune system health
- 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 vegans
- 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
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support healthy pregnancy

### Indication Requirements

- Product presentation must not imply or refer to chronic fatigue syndrome.
- Product presentation must not imply or refer to serious immunological diseases.
- 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: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
- Product presentation must not imply or refer to serious cardiovascular conditions.
- Label statement: If symptoms persist, talk to your health professional.
- 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.

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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).

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Drink plenty of water (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).

If symptoms persist consult your healthcare practitioner (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**

<b>calcium ascorbate dihydrate</b>	<b>99.83 mg</b>
Equivalent: ascorbic acid	80 mg
<b>iron amino acid chelate</b>	<b>120 mg</b>
Equivalent: iron	24 mg
<b>levomefolate calcium</b>	<b>216 microgram</b>
Equivalent: levomefolic acid	200 microgram
<b>mecobalamin (co-methylcobalamin)</b>	<b>500 microgram</b>
<b>pyridoxine hydrochloride</b>	<b>5 mg</b>
Equivalent: pyridoxine	4.12 mg

**Other Ingredients (Excipients)**

- calcium hydrogen phosphate dihydrate
- citric acid
- colloidal anhydrous silica
- croscarmellose sodium
- crospovidone
- disodium edetate
- gellan gum
- hypromellose
- magnesium stearate
- maltodextrin
- microcrystalline cellulose
- potable water
- potassium acetate
- tartaric acid

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