



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

## Public Summary

<b>Summary for ARTG Entry:</b>	375935	Hivita Wellness IRON High Absorption
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Hivita Happy Energy Pty Ltd	
<b>Postal Address</b>	Level 1 60 Toorak Road, South Yarra, VIC, 3141 Australia	
<b>ARTG Start Date</b>	7/10/2021	
<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 . Hivita Wellness IRON High Absorption

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	7/10/2021
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### Permitted Indications

- Maintain/support energy levels
- Maintain/support energy production
- Maintain/support vitality
- Relieve weariness/tiredness/fatigue/feeling of weakness
- Maintain/support general health and wellbeing
- Aid/assist healthy red blood cell production
- Maintain/support red blood cell health
- Maintain/support blood health
- Aid/assist/helps oxygen transport to body tissues
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support cardiovascular system health
- Helps enhance/promote blood vessel health
- Maintain/support immune system health
- Helps enhance/improve/promote immune system function
- Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
- Maintain/support cognitive function/mental function
- Maintain/support nervous system health
- Maintain/support healthy pregnancy
- Maintain/support wound healing

### 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).
- Label statement: If symptoms persist, talk to your health professional.
- Product presentation must not imply or refer to circulatory disorders/diseases/conditions e.g. thrombosis.
- Product presentation must not imply or refer to chronic fatigue syndrome.

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

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 mental illnesses, disorders or conditions.

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 heart disease.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

No Warnings included on Record

#### Additional Product information

#### 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>ascorbic acid</b>	<b>100 mg</b>
<b>calcium folinate</b>	<b>556 microgram</b>
Equivalent: folic acid	400 microgram
<b>iron (II) glycinate</b>	<b>120 mg</b>
Equivalent: iron	24 mg
<b>mecobalamin</b>	<b>500 microgram</b>
<b>pyridoxal 5-phosphate monohydrate</b>	<b>30 mg</b>
Equivalent: pyridoxine	19.14 mg
<b>riboflavin sodium phosphate</b>	<b>15 mg</b>
Equivalent: riboflavin	10.95 mg
<b>thiamine hydrochloride</b>	<b>24.25 mg</b>
Equivalent: thiamine	21.63 mg

#### Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

citric acid

colloidal anhydrous silica

hypromellose

magnesium stearate

maltodextrin

microcrystalline cellulose

povidone

purified water

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