



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	277776	Iron Sustain
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Pty Ltd	
Postal Address	Blackmores Limited, PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	13/07/2016	
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 . Iron Sustain

Product Type	Single Medicine Product	Effective Date	21/10/2025
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Permitted Indications

Maintain/support energy levels
Maintain/support energy production
Relieve weariness/tiredness/fatigue/feeling of weakness
Aid/assist healthy red blood cell production
Helps maintain/support transport of oxygen in the body
Helps maintain/support haemoglobin formation/synthesis
Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
Maintain/support nervous system health
Maintain/support nervous system function

Indication Requirements

Product presentation must not imply or refer to heart disease.
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 mental illnesses, disorders or conditions.
Product presentation must not imply or refer to chronic fatigue syndrome.
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.
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: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications



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No Specific Indications included on Record

Warnings

Not for the treatment of iron deficiency conditions (or words to that effect).

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.
[Contains vitamin B6].

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	200 mg
calcium folinate	135.05 microgram
Equivalent: folic acid	125 microgram
cyanocobalamin	125 microgram
iron (II) glycinate	88.8 mg
Equivalent: iron	24 mg
levomefolate calcium	125 microgram
Equivalent: levomefolic acid	115.4375 microgram
mecobalamin	125 microgram
pyridoxal 5-phosphate monohydrate	24.35 mg
Equivalent: pyridoxine	15 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
calcium phosphate
citric acid
croscarmellose sodium
glycerol
hypromellose
magnesium stearate
maltodextrin
microcrystalline cellulose
potable water
purified water
silicon dioxide
stearic acid

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