



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	286270	Floradix Floravital Herbal Liquid Iron Extract
ARTG entry for	Medicine Listed	
Sponsor	Endeavour CH Pty Ltd	
Postal Address	Endeavour Consumer Health, Level 7 737 Bourke St, Docklands, VIC, 3008 Australia	
ARTG Start Date	1/03/2017	
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 . Floradix Floravital Herbal Liquid Iron Extract

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

Maintain/support energy levels
Maintain/support energy levels when dietary intake is inadequate
Helps convert (state food) into energy
Maintain/support energy production
Maintain/support physical endurance/capacity/stamina
Maintain/support vitality
Relieve weariness/tiredness/fatigue/feeling of weakness when dietary intake is inadequate
Maintain/support healthy growth and development in children
Maintain/support general health and wellbeing
Maintain/support general health and wellbeing in males
Maintain/support general health and wellbeing in growing children
Maintain/support general health and wellbeing in females
Aid/assist healthy red blood cell production
Maintain/support red blood cell health
Maintain/support blood health
Helps maintain/support haemoglobin formation/synthesis
Maintain/support (state vitamin/mineral/nutrient) levels in the body in adolescents
Maintain/support (state vitamin/mineral/nutrient) levels in the body in males
Maintain/support (state vitamin/mineral/nutrient) levels in the body when dietary intake is inadequate in vegetarians
Maintain/support (state vitamin/mineral/nutrient) levels in the body when dietary intake is inadequate
Maintain/support (state vitamin/mineral/nutrient) levels in the body
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when dietary intake is inadequate in adults
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when dietary intake is inadequate in adolescents
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in adolescents
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency in adults
Helps prevent dietary (state vitamin/mineral/nutrient) deficiency when dietary intake is inadequate in children over 12 years of age
Maintain/support nervous system health



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Maintain/support nervous system function
 Maintain/support female reproductive system health

Indication Requirements

Product presentation must not imply or refer to chronic fatigue syndrome.

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).

Product presentation must not imply or refer to mental illnesses, disorders or conditions.

Label statement: If symptoms persist, talk to your health professional.

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 serious cardiovascular 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.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.
 Not for the treatment of iron deficiency conditions (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral

Visual Identification

Active Ingredients

Carum carvi fruit Decoction	754 mg/mL
Equivalent: Carum carvi (Dry)	2.15 mg/mL
cyanocobalamin	86 ng/mL
ferrous gluconate dihydrate	8.64 mg/mL
Equivalent: iron	959 microgram/mL
Hibiscus sabdariffa flower Decoction	754 mg/mL
Equivalent: Hibiscus sabdariffa (Dry)	13.5 mg/mL
Matricaria chamomilla flower Decoction	754 mg/mL
Equivalent: Matricaria chamomilla (Dry)	5.4 mg/mL
pyridoxine hydrochloride	105 microgram/mL
Equivalent: pyridoxine	86 microgram/mL
riboflavin sodium phosphate	113 microgram/mL
Spinacia oleracea leaf Decoction	754 mg/mL
Equivalent: Spinacia oleracea (Dry)	1.62 mg/mL
thiamine hydrochloride	114 microgram/mL

Other Ingredients (Excipients)

ascorbic acid
Black currant
Blackberry



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Cherry
Daucus carota
Grape
maltodextrin
Pear
purified water
Rosa canina

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