



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	286269	Floradix Formula Liquid Herbal 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 Formula Liquid Herbal Iron Extract

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

- 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 in females
- Maintain/support general health and wellbeing
- Maintain/support general health and wellbeing in males
- Maintain/support general health and wellbeing in children
- 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 growing children
- Maintain/support (state vitamin/mineral/nutrient) levels in the body in adolescents
- 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
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when dietary intake is inadequate
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support female reproductive system health

Indication Requirements

Product presentation must not imply or refer to mental illnesses, disorders or conditions.
If product is indicated for supplementation, Label statement: [Vitamins/minerals/nutrients/dietary supplements] can only be of assistance if dietary intake is



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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 chronic fatigue syndrome.

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.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Not suitable for infants under the age of twelve months (or words to that effect).

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

'Contains gluten (or words to that effect)'

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Neither child resistant closure nor restricted flow insert	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

Carum carvi fruit Decoction	592 mg/mL
Equivalent: Carum carvi (Dry)	1.75 mg/mL
cyanocobalamin	60 ng/mL
Daucus carota root Decoction	592 mg/mL
Equivalent: Daucus carota (Dry)	3.5 mg/mL
Elymus repens root Decoction	592 mg/mL
Equivalent: Elymus repens (Dry)	1.97 mg/mL
ferrous gluconate dihydrate	6.76 mg/mL
Equivalent: iron	750 microgram/mL
Hibiscus sabdariffa flower Decoction	592 mg/mL
Equivalent: Hibiscus sabdariffa (Dry)	1.32 mg/mL
Macrocystis pyrifera whole plant Decoction	592 mg/mL
Equivalent: Macrocystis pyrifera (Dry)	1.32 mg/mL
pyridoxine hydrochloride	49 microgram/mL
Equivalent: pyridoxine	40 microgram/mL
riboflavine sodium phosphate	118 microgram/mL
Spinacia oleracea leaf Decoction	592 mg/mL
Equivalent: Spinacia oleracea (Dry)	2.5 mg/mL
thiamine hydrochloride	106 microgram/mL
Urtica dioica leaf Decoction	592 mg/mL

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Equivalent: *Urtica dioica* (Dry)

2.94 mg/mL

Other Ingredients (Excipients)

ascorbic acid

beetroot

Black currant

Blackberry

Cherry

Flavour

Grape

Honey

maltodextrin

orange

Pear

purified water

Rosa canina

Triticum aestivum

Yeast autolysate

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