



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	299718	Chewable Iron
ARTG entry for	Medicine Listed	
Sponsor	Factors Group Australia Pty Ltd	
Postal Address	Unit B 10-16 South Street, Rydalmere, NSW, 2116 Australia	
ARTG Start Date	16/02/2018	
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 . Chewable Iron

Product Type	Single Medicine Product	Effective Date	29/11/2022
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Permitted Indications

- Maintain/support energy levels
- Maintain/support energy production
- 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
- Helps maintain/support transport of oxygen in the body
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support immune system health
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Maintain/support cognitive function/mental function

Indication Requirements

- Product presentation must not imply or refer to chronic fatigue syndrome.
- 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 serious immunological diseases.
- Product presentation must not imply or refer to mental illnesses, disorders or 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.
- Product presentation must not imply or refer to heart disease.
- 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).

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Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

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

Products containing [insert name of sugar alcohol(s)] may have a laxative effect or cause diarrhoea [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
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Components

1 . Formulation 1

Dosage Form Tablet, chewable

Route of Administration Oral

Visual Identification

Active Ingredients

ferric pyrophosphate	38.75 mg
Equivalent: iron	10 mg

Other Ingredients (Excipients)

citric acid
colloidal anhydrous silica
Flavour
lecithin
maltodextrin
purified talc
sodium chloride
sorbitol
stearic acid
xylitol

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