Public Summary

Summary for ARTG Entry:	314849 Liquid Iron
ARTG entry for	Medicine Listed
Sponsor	FIT-BioCeuticals Limited
Postal Address	PO Box 6454, ALEXANDRIA, NSW, 2015 Australia
ARTG Start Date	27/02/2019
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Liquid Iron

Product Type Single Medicine Product **Effective Date** 27/02/2019

Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Relieve weariness/tiredness/fatigue/feeling of weakness when dietary intake is inadequate

Maintain/support healthy growth and development when dietary intake is inadequate in children

Aid/assist healthy red blood cell production

Maintain/support red blood cell health

Helps maintain/support transport of oxygen in the body

Maintain/support healthy immune system function

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 when dietary intake is inadequate

Maintain/support cognitive development when dietary intake is inadequate in children

Maintain/support cognitive function/mental function

Indication Requirements

Product presentation must not imply or refer to serious cardiovascular conditions.

Product presentation must not imply or refer to heart disease.

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

Label statement: Vitamins and minerals can only be of assistance if dietary intake is inadequate OR Vitamin and/or mineral supplements should not replace a balanced diet.

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

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

Product presentation must not imply or refer to neurological conditions or developmental delays.

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

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].

(If the medicine contains one sorbate) Contains [insert name of sorbate] OR (if medicine contains two or more sorbates) Contains sorbates [or words to that effect].

Derived from cow's milk.

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).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral
Visual Identification	

Active Ingredients

bovine lactoferrin	**10 mg/mL**
ferric pyrophosphate	**3.325 mg/mL**
sodium ascorbate	**14.06 mg/mL**
Equivalent: ascorbic acid	12.5 mg/mL

Other Ingredients (Excipients)

citric acid
dextrin
Flavour
glycerol
lecithin
potassium sorbate
purified honey
purified water
sodium chloride

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