Public Summary

Summary for ARTG Entry:	315992 Fe BioActive
ARTG entry for	Medicine Listed
Sponsor	FIT-BioCeuticals Limited
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia
ARTG Start Date	1/04/2019
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.

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 . Fe BioActive

Product Type	Single Medicine Product	**Effective Date**	12/06/2020

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

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

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 serious cardiovascular 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.

Product presentation must not imply or refer to heart disease.

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.

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).

If you are pregnant, or considering becoming pregnant, do not take vitamin A supplements without consulting your doctor or pharmacist.

The recommended daily amount of vitamin A from all sources is 700 micrograms retinol equivalents for women and 900 micrograms retinol equivalents for men.

WARNING - When taken in excess of 3000 micrograms retinol equivalents, vitamin A can cause birth defects.

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Multiple containers	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

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

Arthrospira platensis	**100 mg**
ascorbic acid	**200 mg**
betacarotene	**2.7 mg**
Equivalent: vitamin A	450 RE/microgram
Beta vulgaris root Extract dry concentrate	**30 mg**
Equivalent: Beta vulgaris (Dry)	240 mg
cupric citrate	**545.4 microgram**
Equivalent: copper	200 microgram
iron (II) glycinate	**88.8 mg**
Equivalent: iron	24 mg
levomefolate calcium	**250 microgram**
Equivalent: levomefolic acid	230.875 microgram
mecobalamin (co-methylcobalamin)	**250 microgram**
pyridoxal 5-phosphate monohydrate	**24.59 mg**
Equivalent: pyridoxine	15 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
calcium hydrogen phosphate
citric acid
croscarmellose sodium
dl-alpha-tocopherol
glycerol
hypromellose
magnesium stearate
maize starch
maltodextrin

Public Summary

microcrystalline cellulose
potable water
silicon dioxide
sodium ascorbate
starch sodium octenyl succinate
stearic acid
vegetable oil