



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	300422	Organic Iron Plus
ARTG entry for	Medicine Listed	
Sponsor	Bio-Practica Pty Ltd	
Postal Address	651 Portrush Road, GLEN OSMOND, SA, 5064 Australia	
ARTG Start Date	7/03/2018	
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.

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 . Organic Iron Plus

Product Type	Single Medicine Product	Effective Date	11/05/2020
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Antioxidant/Reduce free radicals formed in the body
- Maintain/support collagen formation
- Helps improve/promote body metabolism/metabolic rate
- Maintain/support energy production
- Maintain/support eye health
- Maintain/support healthy growth and development
- Maintain/support general health and wellbeing
- Maintain/support hair health
- Aid/assist nail growth
- Maintain/support connective tissue health
- Helps enhance/promote connective tissue health
- Aid/assist/helps connective tissue production/formation
- Helps maintain/supports healthy joint cartilage growth/development/production
- Aid/assist healthy red blood cell production
- Helps enhance/promote red blood cell health
- Maintain/support red blood cell health
- Maintain/support blood health
- Helps maintain/support haemoglobin formation/synthesis
- Maintain/support healthy cardiovascular system function
- Maintain/support immune system health
- Enhance/improve/promote immune defence/immunity
- Maintain/support healthy immune system function

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Helps stimulate a healthy immune system response
 Helps prevent dietary (state vitamin/mineral/nutrient) deficiency
 Aid/assist/helps metabolism of (state vitamin/mineral/nutrient)
 Maintain/support cognitive development
 Aid/assist/helps synthesis of neurotransmitters
 Maintain/support nervous system function
 Maintain/support healthy pregnancy
 Maintain/support skin health
 Enhance/improve/promote skin healing
 Maintain/support wound healing
 Enhance/improve/promote skin repair/healing
 Maintain/support skin repair/healing/regeneration

Indication Requirements

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
 Product presentation must not imply or refer to bone disease or disorders e.g. rheumatoid arthritis, juvenile arthritis, debilitating osteoarthritis, osteoporosis.
 Note: this requirement is not intended to apply where the indications referring to osteoporosis specified in column 2 of Table 2 of this instrument are also used.
 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.
 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).
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to serious immunological diseases.
 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.
 Product presentation must not imply or refer to vision correction, faults or serious eye disease e.g. macular degeneration.
 Product presentation must not imply or refer to any form of arthritis or osteoarthritis unless qualified as mild.
 Product presentation must not imply or refer to neurological conditions or developmental delays.

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).
 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.
 Vitamins can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

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

Components

1. Formulation 1

Dosage Form Capsule, hard
Route of Administration Oral

Visual Identification

Active Ingredients

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calcium ascorbate dihydrate	181.6 mg
Equivalent: ascorbic acid	150 mg
calcium folinate	220 microgram
Equivalent: folic acid	200 microgram
hydroxocobalamin	500 microgram
iron (II) glycinate	87.7 mg
Equivalent: iron	24 mg
pyridoxal 5-phosphate monohydrate	7.84 mg
Equivalent: pyridoxine	5 mg
riboflavin sodium phosphate	19.06 mg
Equivalent: riboflavin	15 mg
Rosa canina fruit Extract dry concentrate	16.67 mg
Equivalent: Rosa canina (Dry)	100 mg

Other Ingredients (Excipients)

citric acid
colloidal anhydrous silica
disodium edetate
gellan gum
hypromellose
maltodextrin
microcrystalline cellulose
potable water
potassium acetate
silicon dioxide
stearic acid

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