



**Australian Government**  
**Department of Health**  
 Therapeutic Goods Administration

**Public Summary**

<b>Summary for ARTG Entry:</b>	310189	Orthoplex Iron
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Bio Concepts Pty Ltd	
<b>Postal Address</b>	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
<b>ARTG Start Date</b>	9/10/2018	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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 . Orthoplex Iron**

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	22/01/2021
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**Permitted Indications**

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support collagen formation
- Maintain/support energy production
- Maintain/support general health and wellbeing
- Maintain/support connective tissue health
- Aid/assist/helps connective tissue production/formation
- 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 cardiovascular system health
- Maintain/support blood capillary health
- Maintain/support immune system health
- Maintain/support healthy immune system function
- Maintain/support immune system to fight illness
- Maintain/support absorption of dietary (state vitamin/mineral/nutrient)
- Maintain/support (state vitamin/mineral/nutrient) levels in the body
- Aid/assist/helps synthesis of neurotransmitters
- Maintain/support nervous system health
- Maintain/support nervous system function
- Maintain/support healthy pregnancy
- Maintain/support wound healing in healthy individuals
- Maintain/support skin repair/healing/regeneration in healthy individuals

**Indication Requirements**

If product is indicated for weight loss, label statement: When used in conjunction with a program of reduced intake of dietary calories and increased



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physical activity.

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 circulatory disorders/diseases/conditions e.g. thrombosis.

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

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.

If directed to women, Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

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.

If symptoms persist, seek the advice of a healthcare professional.

Not for the treatment of iron deficiency conditions (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

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>calcium ascorbate dihydrate</b>	<b>145.275 mg</b>
Equivalent: ascorbic acid	120 mg
<b>iron (II) glycinate</b>	<b>106.19 mg</b>
Equivalent: iron	24 mg

**Other Ingredients (Excipients)**

citric acid

colloidal anhydrous silica

disodium edetate

gellan gum

glycine

hypromellose

potable water

potassium acetate

silicon dioxide

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