



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	346486	InNatal Plus Iron
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	FIT-BioCeuticals Pty Ltd	
<b>Postal Address</b>	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
<b>ARTG Start Date</b>	23/10/2020	
<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 . InNatal Plus Iron

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	17/07/2023
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### Permitted Indications

- Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women
- Maintain/support (state vitamin/mineral/nutrient) levels in the body when dietary intake is inadequate in breastfeeding women
- Helps maintains/support healthy foetal CNS/brain development when dietary intake is inadequate
- Helps maintains/support healthy foetal CNS/brain development
- Maintains/support healthy foetal development
- Maintain/support healthy pregnancy
- Maintain/support preconception health

### Indication Requirements

- 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 infertility.
- Label statement: Advise your doctor of any medicine you take during pregnancy, particularly in your first trimester.
- 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.
- WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].
- This medicine contains selenium which is toxic in high doses. A daily dose of 150 micrograms for adults of selenium from dietary supplements should not be exceeded.

### Additional Product information



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**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

**Pack Size/Poison information**

Pack Size	Poison Schedule

**Components**

**1 . Formulation 1**

**Dosage Form** Capsule, soft

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>50 mg</b>
<b>betacarotene</b>	<b>3 mg</b>
<b>Biotin</b>	<b>15 microgram</b>
<b>calcium folinate</b>	<b>191 microgram</b>
Equivalent: folic acid	150 microgram
<b>calcium hydrogen phosphate</b>	<b>84.75 mg</b>
Equivalent: calcium	25 mg
<b>calcium pantothenate</b>	<b>2.73 mg</b>
Equivalent: pantothenic acid	2.5 mg
<b>choline bitartrate</b>	<b>100 mg</b>
<b>chromium picolinate</b>	<b>121 microgram</b>
Equivalent: chromium	15 microgram
<b>colecalfiferol</b>	<b>12.5 microgram</b>
<b>d-alpha-tocopheryl acetate</b>	<b>16.5 mg</b>
<b>inositol</b>	<b>30 mg</b>
<b>iron (II) glycinate</b>	<b>27.8 mg</b>
Equivalent: iron	7.5 mg
<b>levomefolate calcium</b>	<b>108 microgram</b>
Equivalent: levomefolic acid	100 microgram
<b>magnesium phosphate pentahydrate</b>	<b>72.6 mg</b>
Equivalent: magnesium	15 mg
<b>manganese amino acid chelate</b>	<b>10 mg</b>
Equivalent: manganese	1 mg
<b>mecobalamin</b>	<b>1.3 microgram</b>
<b>menaquinone 7</b>	<b>30 microgram</b>
<b>molybdenum trioxide</b>	<b>37.5 microgram</b>
Equivalent: molybdenum	25 microgram
<b>nicotinamide</b>	<b>9 mg</b>
<b>potassium iodide</b>	<b>177 microgram</b>
Equivalent: iodine	135 microgram
<b>pyridoxal 5-phosphate monohydrate</b>	<b>15.7 mg</b>
Equivalent: pyridoxine	10 mg
<b>pyridoxine hydrochloride</b>	<b>18.2 mg</b>
Equivalent: pyridoxine	15 mg
<b>riboflavin sodium phosphate</b>	<b>889 microgram</b>
Equivalent: riboflavin	700 microgram
<b>selenomethionine</b>	<b>43.8 microgram</b>
Equivalent: selenium	17.5 microgram

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<b>thiamine nitrate</b>	<b>864 microgram</b>
Equivalent: thiamine	700 microgram
<b>zinc amino acid chelate</b>	<b>50 mg</b>
Equivalent: zinc	10 mg

**Other Ingredients (Excipients)**

- chlorophyllin-copper complex
- citric acid
- colloidal anhydrous silica
- dl-alpha-tocopherol
- Gelatin
- glycerol
- iron oxide yellow
- lecithin
- maltodextrin
- medium chain triglycerides
- Olive Oil
- purified water
- Soya Oil
- Sunflower Oil
- vegetable oil
- yellow beeswax

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