



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

## Public Summary

<b>Summary for ARTG Entry:</b>	338644	Pure Natal
<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>	30/06/2020	
<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 . Pure Natal

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	7/05/2021
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### Permitted Indications

Maintain/support healthy growth and development  
Maintain/support general health and wellbeing  
Aids/assists healthy bone development/growth/building  
Maintain/support cognitive development  
Maintain/support brain/central nervous system development  
Helps maintains/support healthy foetal CNS/brain development  
Maintains/support healthy foetal development  
Maintain/support healthy pregnancy  
Maintain/support maternal health  
Aid/assist healthy thyroid hormone production for pregnancy  
Maintain/support healthy thyroid gland function for pregnancy

### Indication Requirements

Label statement: If you are concerned about the health of yourself or your baby, talk to your health practitioner.

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.

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

Indication can only be used for medicines that contain iodine as a mandatory component of one or more permitted active ingredients and the recommended daily dose of the medicine provides a minimum of 150 micrograms of iodine.

Product presentation must not imply or refer to any thyroid related diseases.

Label statement: If you have pre-existing thyroid conditions, seek advice from your medical practitioner before taking this medicine.

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 neurological conditions or developmental delays.

### Standard Indications

No Standard Indications included on Record

### Specific Indications



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No Specific Indications included on Record

**Warnings**

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.

If symptoms persist consult your healthcare practitioner (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	Not recorded	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>betacarotene</b>	<b>3 mg</b>
<b>Biotin</b>	<b>300 microgram</b>
<b>calcium ascorbate dihydrate</b>	<b>181.6 mg</b>
Equivalent: calcium	17.07 mg
Equivalent: ascorbic acid	150 mg
<b>calcium hydrogen phosphate dihydrate</b>	<b>6.32 mg</b>
Equivalent: calcium	1.47 mg
<b>calcium pantothenate</b>	<b>40 mg</b>
Equivalent: pantothenic acid	36.64 mg
<b>choline bitartrate</b>	<b>100 mg</b>
<b>chromium nicotinate</b>	<b>200 microgram</b>
Equivalent: chromium	25 microgram
<b>chromium picolinate</b>	<b>200 microgram</b>
Equivalent: chromium	25 microgram
<b>colecalfiferol</b>	<b>.025 mg</b>
<b>colloidal anhydrous silica</b>	<b>10 mg</b>
Equivalent: silicon	4.67 mg
<b>folic acid</b>	<b>200 microgram</b>
<b>inositol</b>	<b>50 mg</b>
<b>iron (II) glycinate</b>	<b>35.4 mg</b>
Equivalent: iron	8 mg
<b>levomefolate calcium</b>	<b>325.38 microgram</b>
Equivalent: levomefolic acid	300 microgram
<b>magnesium ascorbate monohydrate</b>	<b>168 mg</b>
Equivalent: magnesium	10.42 mg
Equivalent: ascorbic acid	150.7 mg
<b>manganese amino acid chelate</b>	<b>10 mg</b>
Equivalent: manganese	1 mg
<b>mecobalamin (co-methylcobalamin)</b>	<b>400 microgram</b>

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<b>menaquinone 7</b>	<b>20 microgram</b>
<b>molybdenum trioxide</b>	<b>75 microgram</b>
Equivalent: molybdenum	50 microgram
<b>nicotinamide</b>	<b>35 mg</b>
<b>phytomenadione</b>	<b>.07 mg</b>
<b>potassium iodide</b>	<b>353.17 microgram</b>
Equivalent: iodine	270 microgram
<b>pyridoxal 5-phosphate</b>	<b>11 mg</b>
Equivalent: pyridoxine	7.53 mg
<b>pyridoxine hydrochloride</b>	<b>30 mg</b>
Equivalent: pyridoxine	24.68 mg
<b>riboflavin sodium phosphate</b>	<b>20 mg</b>
Equivalent: riboflavin	15.2 mg
<b>selenomethionine</b>	<b>150 microgram</b>
Equivalent: selenium	60 microgram
<b>thiamine nitrate</b>	<b>30 mg</b>
Equivalent: thiamine	24.32 mg
<b>zinc citrate dihydrate</b>	<b>38.34 mg</b>
Equivalent: zinc	12.31 mg

**Other Ingredients (Excipients)**

Acacia  
ascorbyl palmitate  
citric acid  
dl-alpha-tocopherol  
hypromellose  
maize starch  
maltodextrin  
medium chain triglycerides  
microcrystalline cellulose  
Pea Starch  
purified water  
silicon dioxide  
sodium alginate  
sucrose

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