



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	338644	Pure Natal
ARTG entry for	Medicine Listed	
Sponsor	Bio Concepts Pty Ltd	
Postal Address	PO Box 190, Banyo, Brisbane, QLD, 4014 Australia	
ARTG Start Date	30/06/2020	
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.

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

Product Type	Single Medicine Product	Effective Date	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

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.

Product presentation must not imply or refer to neurological conditions or developmental delays.

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

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.

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



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No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

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.

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

betacarotene	3 mg
Biotin	300 microgram
calcium ascorbate dihydrate	181.6 mg
Equivalent: calcium	17.07 mg
Equivalent: ascorbic acid	150 mg
calcium hydrogen phosphate dihydrate	6.32 mg
Equivalent: calcium	1.47 mg
calcium pantothenate	40 mg
Equivalent: pantothenic acid	36.64 mg
choline bitartrate	100 mg
chromium nicotinate	200 microgram
Equivalent: chromium	25 microgram
chromium picolinate	200 microgram
Equivalent: chromium	25 microgram
colecalfiferol	.025 mg
colloidal anhydrous silica	10 mg
Equivalent: silicon	4.67 mg
folic acid	200 microgram
inositol	50 mg
iron (II) glycinate	35.4 mg
Equivalent: iron	8 mg
levomefolate calcium	325.38 microgram
Equivalent: levomefolic acid	300 microgram
magnesium ascorbate monohydrate	168 mg
Equivalent: magnesium	10.42 mg
Equivalent: ascorbic acid	150.7 mg
manganese amino acid chelate	10 mg
Equivalent: manganese	1 mg
mecobalamin (co-methylcobalamin)	400 microgram

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