



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	346421	InNatal
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Limited	
Postal Address	Care of Blackmores Ltd PO Box 1725, Warriewood, NSW, 2102 Australia	
ARTG Start Date	22/10/2020	
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 . InNatal

Product Type	Single Medicine Product	Effective Date	14/07/2021
---------------------	-------------------------	-----------------------	------------

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
Helps maintains/support healthy foetal CNS/brain development when dietary intake is inadequate
Maintains/support healthy foetal development
Maintain/support healthy pregnancy
Maintain/support preconception health

Indication Requirements

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 infertility.
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).
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.
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

Pack Size/Poison information

Pack Size	Poison Schedule
------------------	------------------------



Australian Government
Department of Health
Therapeutic Goods Administration

Components

1 . Formulation 1

Dosage Form Capsule, soft

Route of Administration Oral

Visual Identification

Active Ingredients

ascorbic acid	50 mg
betacarotene	3 mg
Biotin	15 microgram
calcium folinate	191 microgram
Equivalent: folic acid	150 microgram
calcium hydrogen phosphate	84.75 mg
Equivalent: calcium	25 mg
calcium pantothenate	2.73 mg
Equivalent: pantothenic acid	2.5 mg
choline bitartrate	100 mg
chromium picolinate	121 microgram
Equivalent: chromium	15 microgram
colecalfiferol	12.5 microgram
d-alpha-tocopheryl acetate	16.5 mg
Equivalent: d-alpha-tocopheryl acetate	22.4 IU
inositol	30 mg
levomefolate calcium	108 microgram
Equivalent: levomefolic acid	100 microgram
magnesium phosphate pentahydrate	72.6 mg
Equivalent: magnesium	15 mg
manganese amino acid chelate	10 mg
Equivalent: manganese	1 mg
mecobalamin (co-methylcobalamin)	1.3 microgram
menaquinone 7	30 microgram
molybdenum trioxide	37.5 microgram
Equivalent: molybdenum	25 microgram
nicotinamide	9 mg
potassium iodide	177 microgram
Equivalent: iodine	135 microgram
pyridoxal 5-phosphate monohydrate	15.7 mg
Equivalent: pyridoxine	10 mg
pyridoxine hydrochloride	18.2 mg
Equivalent: pyridoxine	15 mg
riboflavin sodium phosphate	889 microgram
Equivalent: riboflavin	700 microgram
selenomethionine	43.8 microgram
Equivalent: selenium	17.5 microgram
thiamine nitrate	864 microgram
Equivalent: thiamine	700 microgram
zinc amino acid chelate	50 mg
Equivalent: zinc	10 mg

Other Ingredients (Excipients)

caramel

colloidal anhydrous silica



Australian Government

Department of Health
Therapeutic Goods Administration

dl-alpha-tocopherol
Gelatin
glycerol
lecithin
medium chain triglycerides
Olive Oil
purified water
Soya Oil
Sunflower Oil
vegetable oil
yellow beeswax

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary