



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	346421	InNatal
ARTG entry for	Medicine Listed	
Sponsor	FIT-BioCeuticals Pty Ltd	
Postal Address	Blackmores Limited, 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	25/08/2025
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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

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

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.
WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible.
[Contains vitamin B6].

Additional Product information



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Pack Size/Poison information		
Pack Size	Poison Schedule	
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		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)		



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

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