Public Summary

Summary for ARTG Entry:	312838	Natal Care
ARTG entry for	Medicine Listed	
Sponsor	Biomedica Nutraceuticals Pty Ltd	
Postal Address	PO Box 7052, ALEXANDRIA, NSW, 2015 Australia	
ARTG Start Date	28/12/2018	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Natal Care

Product Type	Single Medicine Product	**Effective Date**	22/02/2019

Permitted Indications

Maintain/support general health and wellbeing in breastfeeding women

Helps maintains/support healthy foetal CNS/brain development

Maintains/support healthy foetal development

Maintain/support healthy pregnancy

Maintain/support maternal health

Help to prevent neural tube defects such as spina bifida and/or anencephaly

Maintain/support preconception health

Maintain/support healthy reproductive hormones

Indication Requirements

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 hormone imbalances.

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

Indication can only be used for medicines that contain folic acid as an active ingredient and the recommended daily dose of the medicine provides a minimum of 400 micrograms of folic acid. Product presentation referring to the prevention of neural tube defects must include at least one of the following label statements: when trying to conceive and during the first trimester of pregnancy, and/or when taken at least four weeks before conception and during the first trimester of pregnancy.

Product presentation must not imply or refer to infertility.

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.

Do not exceed the stated dose except on medical advice. If you have had a baby with a neural tube defect/spina bifida, seek specific medical advice (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule

Components

1 . Formulation 1

Dosage Form	Capsule, hard
Route of Administration	Oral
Visual Identification	

Active Ingredients

ascorbic acid	**82.2 mg**
betacarotene	**3 mg**
Biotin	**100 microgram**
calcium folinate	**54.25 microgram**
Equivalent: folinic acid	50 microgram
calcium pantothenate	**25 mg**
Equivalent: pantothenic acid	22.9 mg
Equivalent: calcium	2.1 mg
calcium phosphate	**53.33 mg**
Equivalent: calcium	20.67 mg
choline bitartrate	**40 mg**
Equivalent: choline	16.5 mg
chromic chloride hexahydrate	**384 microgram**
Equivalent: chromium	75 microgram
chromium picolinate	**201 microgram**
Equivalent: chromium	25 microgram
Citrus bioflavonoids extract	**15 mg**
colecalciferol	**.0125 mg**
copper gluconate	**.357 mg**
Equivalent: copper	.05 mg
cyanocobalamin	**200 microgram**
folic acid	**200 microgram**
inositol	**20 mg**
iron amino acid chelate	**22.5 mg**
Equivalent: iron	4.5 mg
magnesium phosphate pentahydrate	**96.81 mg**
Equivalent: magnesium	20 mg
manganese amino acid chelate	**5 mg**
Equivalent: manganese	500 microgram
molybdenum trioxide	**37.5 microgram**
Equivalent: molybdenum	25 microgram
nicotinamide	**30 mg**
Peppermint Oil	**1 mg**

phytomenadione	**.05 mg**
potassium citrate	**13.83 mg**
Equivalent: potassium	5 mg
potassium iodide	**183 microgram**
Equivalent: iodine	140 microgram
pyridoxal 5-phosphate monohydrate	**10.66 mg**
Equivalent: pyridoxine	6.8 mg
pyridoxine hydrochloride	**22.12 mg**
Equivalent: pyridoxine	18.2 mg
riboflavin	**20 mg**
selenomethionine	**125 microgram**
Equivalent: selenium	50 microgram
thiamine hydrochloride	**25 mg**
zinc citrate dihydrate	**31.1 mg**
Equivalent: zinc	10 mg

Other Ingredients (Excipients)

Acacia
chlorophyllin-copper complex
colloidal anhydrous silica
d-alpha-tocopherol
disodium edetate
fractionated coconut oil
gellan gum
hypromellose
liquid glucose
microcrystalline cellulose
Pea Starch
potassium acetate
purified water
silicon dioxide
sodium alginate
sodium ascorbate
sorbitan monolaurate
stearic acid
sucrose

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