



**Australian Government**  
**Department of Health and Aged Care**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	260743	BLACKMORES PREGNANCY & BREAST-FEEDING GOLD
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Blackmores Ltd	
<b>Postal Address</b>	217-221 Governor Road, Braeside, VIC, 3195 Australia	
<b>ARTG Start Date</b>	8/10/2015	
<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 . BLACKMORES PREGNANCY & BREAST-FEEDING GOLD

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	23/06/2022
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### Permitted Indications

Maintain/support (state vitamin/mineral/nutrient) levels in the body in breastfeeding women

Helps maintains/support healthy foetal CNS/brain development

Maintains/support healthy foetal development

Maintain/support healthy pregnancy

Maintain/support maternal health

Maintain/support maternal health in breastfeeding women

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

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 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.

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

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 any thyroid related diseases.

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

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 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.

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).

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record



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**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 can only be of assistance if the dietary vitamin intake is inadequate. OR Vitamin supplements should not replace a balanced diet.

Drink plenty of water (or words to that effect).

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**

**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, soft

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

ascorbic acid	30 mg
betacarotene	2.4 mg
Biotin	15 microgram
calcium carbonate	125 mg
Equivalent: calcium	50 mg
calcium pantothenate	2.73 mg
Equivalent: pantothenic acid	2.5 mg
chromium picolinate	121 microgram
Equivalent: chromium	15 microgram
colecalfiferol	12.5 microgram
concentrated fish Omega-3 triglycerides	250 mg
Equivalent: docosahexaenoic acid	125 mg
Equivalent: eicosapentaenoic acid	25 mg
cyanocobalamin	1.3 microgram
d-alpha-tocopherol	3.5 mg
folic acid	250 microgram
heavy magnesium oxide	58.1 mg
Equivalent: magnesium	35 mg
iron (II) glycinate	19.22 mg
Equivalent: iron	5 mg
nicotinamide	9 mg
potassium iodide	98.3 microgram
Equivalent: iodine	75 microgram
pyridoxine hydrochloride	1.16 mg
Equivalent: pyridoxine	950 microgram
riboflavin	700 microgram
selenomethionine	81.3 microgram
Equivalent: selenium	32.5 microgram
thiamine nitrate	700 microgram
zinc oxide	6.82 mg

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Equivalent: zinc

5.5 mg

**Other Ingredients (Excipients)**

citric acid  
Gelatin  
glycerol  
hydrogenated vegetable oil  
iron oxide black  
iron oxide red  
lecithin  
maltodextrin  
mannitol  
medium chain triglycerides  
purified water  
Soya Oil  
Sunflower Oil  
vanillin  
vegetable oil  
yellow beeswax

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