



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

## Public Summary

<b>Summary for ARTG Entry:</b>	315610	Eagle Tresos Natal
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	20/03/2019	
<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 . Eagle Tresos Natal

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	1/11/2022
---------------------	-------------------------	-----------------------	-----------

#### Permitted Indications

- Helps maintains/support healthy foetal CNS/brain development
- Maintains/support healthy foetal development
- Maintain/support healthy pregnancy
- Maintain/support maternal health
- Maintain/support preconception health
- Helps prepare the body for pregnancy

#### Indication Requirements

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

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

- Not for the treatment of iron deficiency conditions (or words to that effect).
- WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].
- For practitioner dispensing only.
- 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.
- If symptoms persist, seek the advice of a healthcare professional.

#### Additional Product information



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

**Container information**

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	Not recorded	Not recorded	Not recorded	Child resistant closure	Not recorded

**Pack Size/Poison information**

Pack Size	Poison Schedule

**Components**

**1 . Formulation 1**

**Dosage Form**                      Tablet, film coated

**Route of Administration**      Oral

**Visual Identification**

**Active Ingredients**

<b>ascorbic acid</b>	<b>50 mg</b>
<b>Biotin</b>	<b>400 microgram</b>
<b>borax</b>	<b>2.2 mg</b>
Equivalent: boron	250 microgram
<b>calcium citrate tetrahydrate</b>	<b>236.97 mg</b>
Equivalent: calcium	50 mg
<b>calcium folinate</b>	<b>347 microgram</b>
Equivalent: folinic acid	250 microgram
<b>calcium pantothenate</b>	<b>30 mg</b>
Equivalent: calcium	2.52 mg
Equivalent: pantothenic acid	27.48 mg
<b>choline bitartrate</b>	<b>300 mg</b>
Equivalent: choline	123.39 mg
<b>chromium nicotinate</b>	<b>416 microgram</b>
Equivalent: chromium	50 microgram
<b>colecalfiferol</b>	<b>.025 mg</b>
<b>inositol</b>	<b>40 mg</b>
<b>iron amino acid chelate</b>	<b>37.5 mg</b>
Equivalent: iron	7.5 mg
<b>levomefolate calcium</b>	<b>270.7 microgram</b>
Equivalent: levomefolic acid	250 microgram
<b>magnesium amino acid chelate</b>	<b>100 mg</b>
Equivalent: magnesium	20 mg
<b>manganese amino acid chelate</b>	<b>20 mg</b>
Equivalent: manganese	2 mg
<b>mecobalamin (co-methylcobalamin)</b>	<b>500 microgram</b>
<b>molybdenum trioxide</b>	<b>75 microgram</b>
Equivalent: molybdenum	50 microgram
<b>nicotinamide</b>	<b>30 mg</b>
<b>nicotinic acid</b>	<b>5 mg</b>
<b>phytomenadione</b>	<b>.1 mg</b>
<b>potassium iodide</b>	<b>353.2 microgram</b>
Equivalent: potassium	83.2 microgram
Equivalent: iodine	270 microgram
<b>pyridoxal 5-phosphate monohydrate</b>	<b>10 mg</b>
Equivalent: pyridoxine	6.38 mg
<b>pyridoxine hydrochloride</b>	<b>40 mg</b>
Equivalent: pyridoxine	32.91 mg

Public Summary



Australian Government  
Department of Health and Aged Care  
Therapeutic Goods Administration

<b>riboflavin</b>	<b>30 mg</b>
<b>selenomethionine</b>	<b>124 microgram</b>
Equivalent: selenium	50 microgram
<b>thiamine hydrochloride</b>	<b>30 mg</b>
Equivalent: thiamine	26.75 mg
<b>zinc amino acid chelate</b>	<b>75 mg</b>
Equivalent: zinc	15 mg

**Other Ingredients (Excipients)**

Acacia  
calcium hydrogen phosphate dihydrate  
Carnauba Wax  
chlorophyllin-copper complex  
colloidal anhydrous silica  
croscarmellose sodium  
crospovidone  
d-alpha-tocopherol  
fractionated coconut oil  
hypromellose  
iron oxide black  
liquid glucose  
macrogol 8000  
magnesium stearate  
microcrystalline cellulose  
povidone  
silicon dioxide  
sodium ascorbate  
sucrose  
vanillin

© 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