



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

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

Product Type	Single Medicine Product	Effective Date	24/01/2022
---------------------	-------------------------	-----------------------	------------

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

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.

If symptoms persist, seek the advice of a healthcare professional.

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

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).

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.

Not for the treatment of iron deficiency conditions (or words to that effect).

Public Summary



Australian Government
Department of Health
 Therapeutic Goods Administration

Additional Product information

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

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

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

pyridoxine hydrochloride	40 mg
Equivalent: pyridoxine	32.91 mg
riboflavin	30 mg
selenomethionine	124 microgram
Equivalent: selenium	50 microgram
thiamine hydrochloride	30 mg
Equivalent: thiamine	26.75 mg
zinc amino acid chelate	75 mg
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