



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	318340	Eagle DetoxaChol tablets
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	4/06/2019	
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 DetoxaChol tablets

Product Type	Single Medicine Product	Effective Date	30/04/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Maintain/support natural body cleansing/detoxification processes
- Traditionally used in Western herbal medicine to maintain/support natural liver cleansing/detoxification processes
- Maintain/support natural liver cleansing/detoxification processes
- Traditionally used in Western herbal medicine to aids/assists excretion of metabolic waste products
- Traditionally used in Western herbal medicine to maintain/support general health and wellbeing
- Maintain/support general health and wellbeing
- Traditionally used in Western herbal medicine to maintain/support healthy digestive system function
- Traditionally used in Western herbal medicine to maintain/support digestive system health
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
 - Linked indication - Decrease/reduce/relieve flatulence/carminative
 - Linked indication - Decrease/reduce/relieve abdominal feeling of fullness
 - Linked indication - Decrease/reduce/relieve abdominal bloating/distention
 - Linked indication - Relieve digestive discomfort
- Traditionally used in Western herbal medicine to cholagogue/promote bile flow from gall bladder
- Traditionally used in Western herbal medicine to hepatoprotectant/protect the liver
- Traditionally used in Western herbal medicine to liver tonic/Enhance liver health
- Traditionally used in Western herbal medicine to promote bile flow from liver/chloretic
- Traditionally used in Western herbal medicine to maintain/support healthy liver function
- Traditionally used in Western herbal medicine to maintain/support liver health

Indication Requirements

- Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
- Product presentation must not imply or refer to gastro oesophageal reflux disease.
- Product presentation must only refer to detoxification in relation to natural body processes.
- Product presentation must not imply or refer to drugs/alcohol.
- Product presentation must not imply or refer to disease in any body organ.



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Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
 Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.
 Label statement: If symptoms persist, talk to your health professional.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

For practitioner dispensing only.
 If symptoms persist, seek the advice of a healthcare professional.
 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 use if pregnant or likely to become pregnant (or words to that effect)
 Not recommended for use by pregnant and lactating women (or words to that effect).
 Adults only.
 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.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Tablet, film coated
Route of Administration	Oral

Visual Identification

Active Ingredients

ascorbic acid	20 mg
Brassica oleracea var. italica sprout Powder	75 mg
Equivalent: Brassica oleracea var. italica (Fresh)	1.5 g
calcium folinate	69.44 microgram
Equivalent: folic acid	50 microgram
choline bitartrate	200 mg
Citrus bioflavonoids extract	30 mg
copper gluconate	42.86 microgram
Equivalent: copper	6 microgram
cyanocobalamin	50 microgram
cysteine hydrochloride	28.99 mg
Equivalent: cysteine	20 mg
glutamine	100 mg
glutathione	20 mg
glycine	150 mg
inositol	100 mg
manganese amino acid chelate	250 microgram
Equivalent: manganese	25 microgram
methionine	100 mg
molybdenum trioxide	60 microgram
Equivalent: molybdenum	40 microgram
ornithine monohydrochloride	10 mg
Equivalent: ornithine	7.84 mg
pyridoxal 5-phosphate monohydrate	7.84 mg

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Equivalent: pyridoxine	5 mg
selenomethionine	124.19 microgram
Equivalent: selenium	50 microgram
Silybum marianum fruit Extract dry concentrate standardised	85.71 mg
Equivalent: Silybum marianum (Dry)	6 g
taurine	200 mg
zinc amino acid chelate	25 mg
Equivalent: zinc	5 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
hypromellose
iron oxide black
iron oxide red
macrogol 400
macrogol 8000
magnesium stearate
maize starch
microcrystalline cellulose
Peppermint Oil
silicon dioxide
soy polysaccharide
titanium dioxide

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