



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

## Public Summary

|                                |  |                           |
|--------------------------------|--|---------------------------|
| <b>Summary for ARTG Entry:</b> | 370981   | Eagle Clinical DetoxaChol |
| <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<br>Australia |                           |
| <b>ARTG Start Date</b>         | 13/07/2021   |                           |
| <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 Clinical DetoxaChol

| Product Type | Single Medicine Product | Effective Date | 2/12/2022 |
|--------------|-------------------------|----------------|-----------|
|--------------|-------------------------|----------------|-----------|

### 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
- Maintain/support natural liver cleansing/detoxification processes
- Traditionally used in Western herbal medicine to 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 abdominal bloating/distention
  - Linked indication - Relieve digestive discomfort
  - Linked indication - Decrease/reduce/relieve abdominal feeling of fullness
  - Linked indication - Decrease/reduce/relieve flatulence/carminative
- 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 only refer to detoxification in relation to natural body processes.
- 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 drugs/alcohol.
- Product presentation must not imply or refer to disease in any body organ.
- Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

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Label statement: If symptoms persist, talk to your health professional.

Product presentation must not imply or refer to gastro oesophageal reflux disease.

Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

**Standard Indications**

No Standard Indications included on Record

**Specific Indications**

No Specific Indications included on Record

**Warnings**

Not recommended for use by pregnant and lactating women (or words to that effect).

Adults only.

For practitioner dispensing 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.

WARNING - Stop taking this medication if you experience tingling, burning or numbness and see your healthcare practitioner as soon as possible. [Contains vitamin B6].

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)

**Additional Product information**

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

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|  |                         |
|--|-------------------------|
| Equivalent: ornithine  | 7.84 mg                 |
| <b>pyridoxal 5-phosphate monohydrate</b>                           | <b>7.84 mg</b>          |
| Equivalent: pyridoxine   | 5 mg                    |
| <b>selenomethionine</b>  | <b>124.19 microgram</b> |
| Equivalent: selenium   | 50 microgram            |
| <b>Silybum marianum fruit Extract dry concentrate standardised</b> | <b>85.71 mg</b>         |
| Equivalent: Silybum marianum (Dry)                                 | 6 g                     |
| <b>taurine</b>   | <b>200 mg</b>           |
| <b>zinc amino acid chelate</b>                                     | <b>25 mg</b>            |
| 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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