



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	214847	ETHICAL NUTRIENTS LIVER DETOX AND SUPPORT
ARTG entry for	Medicine Listed	
Sponsor	Metagenics (Aust) Pty Ltd	
Postal Address	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
ARTG Start Date	20/09/2013	
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 . ETHICAL NUTRIENTS LIVER DETOX AND SUPPORT

Product Type	Single Medicine Product	Effective Date	5/02/2021
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Traditionally used in Chinese medicine to maintain/support natural liver cleansing/detoxification processes
- Traditionally used in Ayurvedic medicine to 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 hepatoprotectant/protect the liver
- Traditionally used in Chinese medicine to hepatoprotectant/protect the liver
- Traditionally used in Western herbal medicine to maintain/support bile production
- Traditionally used in Ayurvedic medicine to maintain/support bile production
- Maintain/support bile production
- Traditionally used in Chinese medicine to maintain/support healthy liver function
- Traditionally used in Western herbal medicine to maintain/support healthy liver function
- Traditionally used in Ayurvedic medicine to maintain/support healthy liver function
- Maintain/support liver health
- Traditionally used in Ayurvedic medicine to maintain/support liver health
- Maintain/support (state vitamin/mineral/nutrient) levels in the body

Indication Requirements

- 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).
- Product presentation must not imply or refer to drugs/alcohol.
- Product presentation must only refer to detoxification in relation to natural body processes.
- Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.
- Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
- Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Standard Indications

No Standard Indications included on Record

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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].

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 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**

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Curcuma longa rhizome Extract dry concentrate	50 mg
Equivalent: Curcuma longa (Dry)	1.25 g
cyanocobalamin	200 microgram
folic acid	200 microgram
pyridoxine hydrochloride	50 mg
Equivalent: pyridoxine	41.14 mg
Rosmarinus officinalis leaf Extract dry concentrate	200 mg
Equivalent: Rosmarinus officinalis (Dry)	1 g
Schisandra chinensis fruit Extract dry concentrate	375 mg
Equivalent: Schisandra chinensis (Dry)	1.5 g
selenomethionine	186.4 microgram
Equivalent: selenium	75 microgram
Silybum marianum fruit Extract dry concentrate	200 mg
Equivalent: Silybum marianum (Dry)	14 g
taurine	500 mg

Other Ingredients (Excipients)

- calcium hydrogen phosphate dihydrate
- carmellose
- Carnauba Wax
- chlorophyllin-copper complex
- colloidal anhydrous silica
- croscarmellose sodium
- hypromellose
- macrogol 8000
- magnesium stearate
- microcrystalline cellulose

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