



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	317275	Herbal Liver Support
ARTG entry for	Medicine Listed	
Sponsor	Lyndelen Pty Ltd T/A The Herbal Extract Co of Australia	
Postal Address	PO Box 107, PANANIA, NSW, 2213 Australia	
ARTG Start Date	7/05/2019	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Herbal Liver Support

Product Type	Single Medicine Product	Effective Date	19/11/2019 2:48:53 PM
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Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- Helps maintain/support body's natural channels of elimination
- Maintain/support natural body cleansing/detoxification processes
- Aids/assists body's natural channels of elimination
- Aids/assists natural cleansing/detoxification processes of the gastrointestinal system/gut
- Maintain/support natural cleansing/detoxification processes of the gastrointestinal system/gut
- Maintain/support natural liver cleansing/detoxification processes
- Aids/assists body waste elimination
- Maintain/support body waste elimination
- Helps enhance/promote general health and wellbeing
- Maintain/support general health and wellbeing
- Helps in the maintenance of healthy blood lipids/blood fats
- Helps maintain/support healthy cholesterol
- Reduce occurrence of excess intestinal wind/gas
- Decrease/reduce/relieve excess intestinal gas
- Decrease/reduce/relieve flatulence/carminative
- Decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Linked indication - Relieve digestive discomfort
- Linked indication - Helps reduce occurrence of symptoms of indigestion/dyspepsia

Public Summary



Australian Government
Department of Health
 Therapeutic Goods Administration

Linked indication - Maintain/support digestive system health
 Linked indication - Maintain/support healthy digestion
 Linked indication - Maintain/support healthy digestive system function
 Linked indication - Helps enhance/promote healthy digestive system function
 Linked indication - Antiemetic/Decrease/reduce/relieve vomiting
 Linked indication - Decrease/reduce/relieve nausea
 Decrease/reduce/relieve symptoms of heartburn
 Maintain/support gallbladder function
 Maintain/support gallbladder health
 Hepatoprotectant/protect the liver
 Traditionally used in Western herbal medicine to maintain/support healthy liver regeneration
 Traditionally used in Western herbal medicine to liver tonic/Enhance liver health
 Maintain/support healthy liver function
 Maintain/support liver health
 Traditionally used in Western herbal medicine to aid/assist healthy liver regeneration

Indication Requirements

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.
 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 gastro oesophageal reflux disease.
 Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.
 Label statement: If symptoms persist, talk to your health professional.
 Product presentation must not imply or refer to disease in any body organ.
 Product presentation must not imply or refer to lowering blood lipids, blood fats and triglycerides.
 Product presentation must not imply or refer to lowering or raising blood cholesterol levels from outside of the normal healthy range
 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

Contains ethanol or contains alcohol.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form	Oral Liquid
Route of Administration	Oral

Visual Identification

Active Ingredients

Bupleurum falcatum root Extract liquid	30 mg/mL
Equivalent: Bupleurum falcatum (Dry)	30 mg/mL
Cynara scolymus leaf Extract liquid	300 mg/mL
Equivalent: Cynara scolymus (Dry)	300 mg/mL
Rosmarinus officinalis leaf Extract liquid	15 mg/mL
Equivalent: Rosmarinus officinalis (Dry)	15 mg/mL
Schisandra chinensis fruit Extract liquid	65 mg/mL
Equivalent: Schisandra chinensis (Dry)	65 mg/mL
Silybum marianum seed Extract liquid	150 mg/mL

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

Equivalent: Silybum marianum (Dry)	150 mg/mL
Taraxacum officinale root Extract liquid	140 mg/mL
Equivalent: Taraxacum officinale (Dry)	140 mg/mL

Other Ingredients (Excipients)

Anise Oil

glycerol

Peppermint Oil

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Public Summary