



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	216264	Legalon
ARTG entry for	Medicine Listed	
Sponsor	SFI Australasia	
Postal Address	PO Box 1027, CROWS NEST, NSW, 1585 Australia	
ARTG Start Date	21/10/2013	
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 . Legalon

Product Type	Single Medicine Product	Effective Date	28/06/2024
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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 liver cleansing/detoxification processes
Relieve weariness/tiredness/fatigue/feeling of weakness
Maintain/support general health and wellbeing
Anti-inflammatory/relieve inflammation
Helps reduce occurrence of symptoms of indigestion/dyspepsia
Decrease/reduce/relieve abdominal feeling of fullness
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
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
Decrease/reduce/relieve nausea

Indication Requirements

Product presentation must not imply or refer to liver disease, such as cirrhosis, hepatitis.

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 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 drugs/alcohol.

Product presentation must not imply or refer to chronic fatigue syndrome.

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

Standard Indications



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No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist consult your healthcare practitioner (or words to that effect).

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Silybum marianum fruit Extract dry concentrate standardised	180 mg
Equivalent: Silybum marianum (Dry)	7.2 g

Other Ingredients (Excipients)

Gelatin
iron oxide black
iron oxide red
magnesium stearate
maize starch
microcrystalline cellulose
sodium lauryl sulfate
sodium starch glycollate
titanium dioxide

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