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.

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 . Legalon

Product Type Single Medicine Product **Effective Date** 19/11/2019 2:48:57 PM

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

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

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.

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 chronic fatigue syndrome.

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

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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