



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	293910	MediHerb Silymarin
ARTG entry for	Medicine Listed	
Sponsor	Integria Healthcare Australia Pty Ltd	
Postal Address	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
ARTG Start Date	15/09/2017	
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 . MediHerb Silymarin

Product Type	Single Medicine Product	Effective Date	5/03/2021
---------------------	-------------------------	-----------------------	-----------

Permitted Indications

- Antioxidant/Reduce free radicals formed in the body
- Helps reduce/decrease free radical damage to body cells
- 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
- Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
- 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 abdominal bloating/distention
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal feeling of fullness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
 - Linked indication - Decrease/reduce/relieve flatulence/carminative
 - Linked indication - Decrease/reduce/relieve abdominal bloating/distention
 - Linked indication - Relieve digestive discomfort
 - Linked indication - Decrease/reduce/relieve abdominal feeling of fullness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to relieve digestive discomfort
- Traditionally used in Western herbal medicine to cholagogue/promote bile flow from gall bladder
- Traditionally used in Western herbal medicine to helps enhance/improve/promote/increase bile secretion/flow
- Traditionally used in Western herbal medicine to helps enhance/promote healthy liver function
- 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 maintain/support bile production
- 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 not imply or refer to gastro oesophageal reflux disease.

Public Summary



Australian Government
Department of Health
Therapeutic Goods Administration

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

Product presentation must not imply or refer to drugs/alcohol.

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

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.

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

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

For practitioner dispensing only.

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

If symptoms persist, seek the advice of a healthcare professional.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
-----------	-----------------

Components

1 . Formulation 1

Dosage Form Tablet, uncoated

Route of Administration Oral

Visual Identification

Active Ingredients

Silybum marianum seed Extract dry concentrate standardised	240 mg
---	---------------

Equivalent: Silybum marianum (Dry)	16.8 g
------------------------------------	--------

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

magnesium stearate

microcrystalline cellulose

sodium starch glycollate

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary