



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

<b>Summary for ARTG Entry:</b>	293910	MediHerb Silymarin
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	15/09/2017	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	5/03/2021
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### 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  
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 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

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



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

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

Product presentation must not encourage excessive or harmful consumption of alcohol or other toxic substances.

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 disease in any body organ.

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

#### 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

<b>Silybum marianum seed Extract dry concentrate standardised</b>	<b>240 mg</b>
Equivalent: Silybum marianum (Dry)	16.8 g

##### Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

magnesium stearate

microcrystalline cellulose

sodium starch glycollate

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