



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

## Public Summary

<b>Summary for ARTG Entry:</b>	168011	METAGENICS SILYMARIN IC
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Metagenics (Aust) Pty Ltd	
<b>Postal Address</b>	PO Box 675, VIRGINIA BC, QLD, 4014 Australia	
<b>ARTG Start Date</b>	14/01/2010	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	Listed Medicines	

### Conditions

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 . METAGENICS SILYMARIN IC

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	25/04/2020
---------------------	-------------------------	-----------------------	------------

#### 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 body cleansing/detoxification processes  
Hepatoprotectant/protect the liver  
Traditionally used in Western herbal medicine to maintain/support bile production  
Maintain/support healthy liver function  
Traditionally used in Western herbal medicine to maintain/support healthy liver function  
Maintain/support liver health

#### Indication Requirements

Product presentation must only refer to detoxification in relation to natural body processes.  
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 encourage excessive or harmful consumption of alcohol or other toxic substances.  
Product presentation must not imply or refer to drugs/alcohol.

#### 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

<b>Pack Size</b>	<b>Poison Schedule</b>
------------------	------------------------

#### Components

##### 1 . Formulation 1



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

**Dosage Form** Capsule, hard

**Route of Administration** Oral

**Visual Identification**

**Active Ingredients**

**Silybum marianum** 210 mg

**Other Ingredients (Excipients)**

calcium hydrogen phosphate dihydrate

colloidal anhydrous silica

disodium edetate

gellan gum

hypromellose

magnesium stearate

microcrystalline cellulose

potable water

potassium acetate

© 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