



Australian Government

Department of Health, Disability and Ageing
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	203654	St Mary's Thistle 35 000
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	Suite 802 Level 8 1-5 Chalmers Crescent Mascot, Sydney, NSW, 2020 Australia	
ARTG Start Date	5/12/2012	
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 . St Mary's Thistle 35 000

Product Type	Single Medicine Product	Effective Date	6/09/2025
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body

Maintain/support healthy digestion

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 - Decrease/reduce/relieve loss of appetite

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 maintain/support gallbladder health

Hepatoprotectant/protect the liver

Traditionally used in Western herbal medicine to hepatoprotectant/protect the liver.

Maintain/support healthy liver function

Traditionally used in Western herbal medicine to maintain/support healthy liver function

Maintain/support liver health

Traditionally used in Western herbal medicine to maintain/support liver health

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 gastro oesophageal reflux disease.

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

Product presentation must not imply or refer to disease in any body organ.

Product presentation must not imply or refer to eating disorders.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record



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Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Silybum marianum seed Extract dry concentrate standardised	500 mg
Equivalent: Silybum marianum (Dry)	35 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
Carnauba Wax
colloidal anhydrous silica
croscarmellose sodium
hypromellose
macrogol 400
magnesium stearate
microcrystalline cellulose
povidone

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