



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	351740	MediHerb LivCo
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	15/12/2020	
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 LivCo

Product Type	Single Medicine Product	Effective Date	3/03/2021
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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 general health and wellbeing
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 symptoms of indigestion/dyspepsia
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
Linked indication - Decrease/reduce/relieve excess intestinal gas
Linked indication - Decrease/reduce/relieve abdominal feeling of fullness
Linked indication - Relieve digestive discomfort
Linked indication - Decrease/reduce/relieve abdominal bloating/distention
Linked indication - Decrease/reduce/relieve flatulence/carminative
Traditionally used in Western herbal medicine to decrease/reduce/relieve digestive spasms
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 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
Traditionally used in Western herbal medicine to antispasmodic/spasmodic

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.

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Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

For practitioner dispensing only.
If symptoms persist, seek the advice of a healthcare professional.

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Rosmarinus officinalis leaf Extract dry concentrate	66.67 mg
Equivalent: Rosmarinus officinalis (Dry)	500 mg
Schisandra chinensis fruit Extract dry concentrate	167 mg
Equivalent: Schisandra chinensis (Dry)	1.002 g
Silybum marianum seed Extract dry concentrate standardised	34 mg
Equivalent: Silybum marianum (Dry)	2.38 g

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
disodium edetate
gellan gum
hypromellose
magnesium stearate
microcrystalline cellulose
potable water
potassium acetate
sodium starch glycollate

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