



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	209649	Liver Care
ARTG entry for	Medicine Listed	
Sponsor	Herbs of Gold Pty Ltd	
Postal Address	PO Box 3143, KIRRAWEE, NSW, 2232 Australia	
ARTG Start Date	17/05/2013	
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.

The sponsor of the listed medicine must not, by any means, intentionally or recklessly advertise the medicine for an indication other than those accepted in relation to the inclusion of the medicine in the Register.

The sponsor shall not supply the listed medicine after the expiry date of the goods.

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 . Liver Care

Product Type	Single Medicine Product	Effective Date	5/06/2020
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Permitted Indications

Antioxidant/Reduce free radicals formed in the body
Traditionally used in Western herbal medicine to orexigenic/improve/promote healthy appetite
Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
Traditionally used in Western herbal medicine to decrease/reduce/relieve constipation
Traditionally used in Western herbal medicine to aperient/laxative
Traditionally used in Western herbal medicine to enhance/promote healthy digestion
Traditionally used in Western herbal medicine to maintain/support healthy digestion
Maintain/support healthy digestion
Traditionally used in Western herbal medicine to stimulates/increases digestive gastric hydrochloric acid secretion
Traditionally used in Western herbal medicine to bitter tonic/stimulate gastric secretions
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 digestive tonic/Improve digestive weakness
Traditionally used in Western herbal medicine to cholagogue/promote bile flow from gall bladder
Traditionally used in Western herbal medicine to hepatoprotectant/protect the liver
Hepatoprotectant/protect the liver
Traditionally used in Western herbal medicine to promote bile flow from liver/chloretic
Traditionally used in Western herbal medicine to maintain/support healthy liver function
Maintain/support healthy liver function
Maintain/support liver health
Traditionally used in Western herbal medicine to maintain/support liver health

Indication Requirements



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Label statement: Drink plenty of water (or words to that effect).

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

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

Product presentation must not imply or refer to gastro oesophageal reflux disease.

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

Label statement for stimulant laxatives: Prolonged use may cause serious bowel problems.

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

Product presentation must not imply or refer to eating disorders.

Label statement: Do not use when abdominal pain, nausea or vomiting are present or if you develop diarrhoea. If you are pregnant or breastfeeding - seek the advice of a healthcare professional before taking this product (or words to that effect).

Product presentation must not refer to or imply weight loss.

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

1 . Formulation 1

Dosage Form Tablet, film coated

Route of Administration Oral

Visual Identification

Active Ingredients

Bupleurum falcatum root Extract dry concentrate	50 mg
Equivalent: Bupleurum falcatum (Dry)	500 mg
choline bitartrate	75 mg
curcumin	50 mg
inositol	50 mg
Schisandra chinensis fruit Extract dry concentrate	187.5 mg
Equivalent: Schisandra chinensis (Dry)	750 mg
Silybum marianum fruit Extract dry concentrate standardised	50 mg
Equivalent: Silybum marianum (Dry)	3.5 g
Taraxacum officinale root Extract dry concentrate	300 mg
Equivalent: Taraxacum officinale (Dry)	1.5 g
taurine	100 mg

Other Ingredients (Excipients)

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

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