



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	76394	MediHerb Golden Seal
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	9/10/2000	
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 Golden Seal

Product Type	Single Medicine Product	Effective Date	1/05/2021
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Permitted Indications

- Traditionally used in Western herbal medicine to alterative/blood cleanser/depurative/purifier
- Traditionally used in Western herbal medicine to maintain/support body mucous membrane health
- Traditionally used in Western herbal medicine to anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to decrease/reduce/relieve loss of appetite
- Traditionally used in Western herbal medicine to maintain/support healthy appetite
- Traditionally used in Western herbal medicine to enhance/promote healthy digestion
- Traditionally used in Western herbal medicine to maintain/support healthy mucous linings of the digestive system
- Traditionally used in Western herbal medicine to bitter tonic/stimulate gastric secretions
- Traditionally used in Western herbal medicine to maintain/support gastrointestinal system health
- Traditionally used in Western herbal medicine to helps enhance/promote gastrointestinal system health
- Traditionally used in Western herbal medicine to maintain/support gastrointestinal mucosal membrane 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 abdominal bloating/distention
 - Linked indication - Reduce occurrence of excess intestinal wind/gas
- Traditionally used in Western herbal medicine to helps decrease/reduce/relieve mild gastrointestinal tract inflammation
- Traditionally used in Western herbal medicine to promote bile flow from liver/chloretic
- Traditionally used in Western herbal medicine to decrease/reduce heavy menstruation/periods
- Traditionally used in Western herbal medicine to decrease/reduce excess mucous
- Traditionally used in Western herbal medicine to maintain/support healthy mucous membranes/mucous tissue of the respiratory tract
- Traditionally used in Western herbal medicine to soothe/relieve skin inflammation
- Traditionally used in Western herbal medicine to maintain/support skin health

Indication Requirements

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



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Product presentation must not imply or refer to eating disorders.

Product presentation must not imply or refer to serious forms of respiratory disorders/diseases, such as: asthma, pneumonia, COAD, COPD, influenza.

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

Product presentation must not imply or refer to disease in any body organ, in particular the kidney or liver.

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

If symptoms persist, seek the advice of a healthcare professional.

If diarrhoea persists for more than 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3-6 years or 48 hours in adults and children over 6 years, seek medical advice (or words to that effect).

Do not use if pregnant or likely to become pregnant (or words to that effect)

If symptoms persist consult your healthcare practitioner (or words to that effect).

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

hydrastis canadensis root and rhizome Extract liquid	1.5 mL
Equivalent: hydrastis canadensis (Dry)	500 mg

Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate
colloidal anhydrous silica
hypromellose
magnesium stearate
microcrystalline cellulose
sodium starch glycollate

Public Summary

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