



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

## Public Summary

<b>Summary for ARTG Entry:</b>	371100	MediHerb Golden Seal
<b>ARTG entry for</b>	Medicine Listed	
<b>Sponsor</b>	Integria Healthcare Australia Pty Ltd	
<b>Postal Address</b>	PO Box 4854, EIGHT MILE PLAINS, QLD, 4113 Australia	
<b>ARTG Start Date</b>	15/07/2021	
<b>Product Category</b>	Medicine	
<b>Status</b>	Active	
<b>Approval Area</b>	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

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	21/07/2021
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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

Linked indication - Reduce occurrence of excess intestinal wind/gas

Linked indication - Decrease/reduce/relieve abdominal bloating/distention

Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia

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 eating disorders.

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

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



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Product presentation must only refer to detoxification in relation to natural body processes.

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 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 imply or refer to drugs/alcohol.

#### Standard Indications

No Standard Indications included on Record

#### Specific Indications

No Specific Indications included on Record

#### Warnings

For practitioner dispensing only.

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

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

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
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Route of Administration	Oral
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#### Visual Identification

#### Active Ingredients

hydrastis canadensis root and rhizome Extract dry concentrate	277 mg
Equivalent: hydrastis canadensis (Dry)	500 mg

#### Other Ingredients (Excipients)

calcium hydrogen phosphate dihydrate  
colloidal anhydrous silica  
croscarmellose sodium  
hypromellose  
magnesium stearate  
maltodextrin  
microcrystalline cellulose  
silicon dioxide  
sodium starch glycollate

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