



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

## Public Summary

<b>Summary for ARTG Entry:</b>	332793	MediHerb HiPep
<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>	30/03/2020	
<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 HiPep

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	29/01/2021
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### Permitted Indications

- Anti-inflammatory/relieve inflammation
- Traditionally used in Western herbal medicine to demulcent/soothe irritated tissues
- Traditionally used in Western herbal medicine to maintain/support healthy mucous linings of the digestive system
- 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 - Decrease/reduce/relieve abdominal spasm
  - Linked indication - Decrease/reduce/relieve abdominal bloating/distention
  - Linked indication - Decrease/reduce/relieve abdominal cramping
  - Linked indication - Decrease/reduce/relieve flatulence/carminative
- Traditionally used in Western herbal medicine to relieve digestive discomfort
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of heartburn
- Traditionally used in Western herbal medicine to helps decrease/reduce/relieve mild gastrointestinal tract inflammation
- Traditionally used in Western herbal medicine to soothe gastro-intestinal tract mucous membranes
- Traditionally used in Western herbal medicine to maintain/support stomach function
- Traditionally used in Western herbal medicine to maintain/support stomach 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 gastro oesophageal reflux disease.
- Product presentation must not imply or refer to serious musculoskeletal or neurological conditions.
- Product presentation must not imply or refer to disease in any body organ.

### Standard Indications

No Standard Indications included on Record

### Specific Indications

No Specific Indications included on Record

### Warnings



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For practitioner dispensing only.

Contains methyl salicylate

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

**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**

<b>Filipendula ulmaria herb Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Filipendula ulmaria (Dry)	500 mg
<b>Glycyrrhiza glabra root Extract dry concentrate standardised</b>	<b>125 mg</b>
Equivalent: Glycyrrhiza glabra (Dry)	3.44 g
<b>Matricaria chamomilla flower Extract dry concentrate</b>	<b>100 mg</b>
Equivalent: Matricaria chamomilla (Dry)	600 mg
<b>Matricaria chamomilla flower Oil essential</b>	<b>5 mg</b>

**Other Ingredients (Excipients)**

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

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