



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

## Public Summary

<b>Summary for ARTG Entry:</b>	330721	Eagle Vegie Digestaid
<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>	4/03/2020	
<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.

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 . Eagle Vegie Digestaid

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	4/03/2020
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### Permitted Indications

Traditionally used in Western herbal medicine to maintain/support general health and wellbeing  
Traditionally used in Western herbal medicine to maintain/support healthy appetite  
Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative  
Traditionally used in Western herbal medicine to maintain/support healthy digestive system function  
Maintain/support healthy digestive system function  
Maintain/support digestion/assimilation of nutrients  
Aid/assist/helps digestion of (state nutrient)  
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention  
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal cramping  
Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal spasm  
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia  
Linked indication - Decrease/reduce/relieve flatulence/carminative  
Linked indication - Decrease/reduce/relieve abdominal spasm  
Linked indication - Decrease/reduce/relieve abdominal cramping  
Linked indication - Decrease/reduce/relieve abdominal bloating/distention  
Traditionally used in Western herbal medicine to relieve digestive discomfort  
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

### 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 liver disease, such as cirrhosis, hepatitis.



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Product presentation must not imply or refer to eating disorders.

**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**

<b>Amylase</b>	<b>15 thousand DU</b>
<b>bromelains</b>	<b>2.4 million PU</b>
<b>cellulase</b>	<b>300 CU</b>
<b>lipase</b>	<b>1.2 thousand LipU</b>
<b>protease</b>	<b>50 Thousand HUT</b>
<b>Taraxacum officinale root Extract dry concentrate</b>	<b>166.25 mg</b>
Equivalent: Taraxacum officinale (Dry)	665 mg
<b>tilactase</b>	<b>1.5 thousand ALU</b>
<b>Zingiber officinale root Extract dry concentrate</b>	<b>41.625 mg</b>
Equivalent: Zingiber officinale (Dry)	333 mg

**Other Ingredients (Excipients)**

- Acacia
- colloidal anhydrous silica
- gellan gum
- hypromellose
- magnesium carbonate hydrate
- maltodextrin
- medium chain triglycerides
- microcrystalline cellulose
- potable water

Public Summary

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