



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

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

Product Type	Single Medicine Product	Effective Date	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

- Product presentation must not imply or refer to gastro oesophageal reflux disease.
- Label statement: If symptoms persist, talk to your health professional.
- 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

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

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