



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	328162	Floradix Gallexier Digestive Aid
ARTG entry for	Medicine Listed	
Sponsor	Endeavour CH Pty Ltd	
Postal Address	Endeavour Consumer Health, Level 7 737 Bourke St, Docklands, VIC, 3008 Australia	
ARTG Start Date	2/01/2020	
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.

All reports of adverse reactions or similar experiences associated with the use or administration of the listed medicine shall be notified to the Head, Office of Product Review, Therapeutic Goods Administration, as soon as practicable after the sponsor of the goods becomes aware of those reports. Sponsors of listed medicines must retain records of such reports for a period of not less than 18 months from the day the Head, Office of Product Review is notified of the report or reports.

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 . Floradix Gallexier Digestive Aid

Product Type	Single Medicine Product	Effective Date	2/01/2020
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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 digestion
- Traditionally used in Western herbal medicine to maintain/support healthy digestion
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal bloating/distention
- Traditionally used in Western herbal medicine to decrease/reduce/relieve abdominal feeling of fullness
- Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
- Traditionally used in Western herbal medicine to relieve digestive discomfort

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

(If medicine contains one sugar) contains [insert name of sugar] OR (If medicine contains two or more sugars) Contains sugars [or words to that effect].

Additional Product information



Australian Government
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Pack Size/Poison information

Pack Size

Poison Schedule

Components

1 . Formulation 1

Dosage Form Oral Liquid

Route of Administration Oral

Visual Identification

Active Ingredients

Achillea millefolium herb Decoction	809 mg/mL
Equivalent: Achillea millefolium (Dry)	5.9 mg/mL
Citrus aurantium fruit peel Decoction	809 mg/mL
Equivalent: Citrus aurantium (Dry)	3 mg/mL
Cnicus benedictus herb Decoction	809 mg/mL
Equivalent: Cnicus benedictus (Dry)	1.83 mg/mL
Curcuma longa rhizome Decoction	809 mg/mL
Equivalent: Curcuma longa (Dry)	5.9 mg/mL
Cynara scolymus leaf Decoction	809 mg/mL
Equivalent: Cynara scolymus (Dry)	32.5 mg/mL
Elettaria cardamomum fruit Decoction	809 mg/mL
Equivalent: Elettaria cardamomum (Dry)	.75 mg/mL
Foeniculum vulgare fruit Decoction	809 mg/mL
Equivalent: Foeniculum vulgare (Dry)	3.7 mg/mL
Gentiana lutea root Decoction	809 mg/mL
Equivalent: Gentiana lutea (Dry)	8.2 mg/mL
Matricaria chamomilla flower Decoction	809 mg/mL
Equivalent: Matricaria chamomilla (Dry)	3.7 mg/mL
Menyanthes trifoliata leaf Decoction	809 mg/mL
Equivalent: Menyanthes trifoliata (Dry)	.75 mg/mL
Taraxacum officinale leaf Decoction	809 mg/mL
Equivalent: Taraxacum officinale (Dry)	10.3 mg/mL
Zingiber officinale rhizome Decoction	809 mg/mL
Equivalent: Zingiber officinale (Dry)	4 mg/mL

Other Ingredients (Excipients)

fructose

lactic acid

purified water

Public Summary

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