



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	291400	Gutelix
ARTG entry for	Medicine Listed	
Sponsor	The Pharmaceutical Plant Company Pty Ltd	
Postal Address	3 Sigma Drive, Croydon South, VIC, 3136 Australia	
ARTG Start Date	12/07/2017	
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.

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 . Gutelix

Product Type	Single Medicine Product	Effective Date	26/01/2021
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Permitted Indications

Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative
Traditionally used in Western herbal medicine to decrease/reduce/relieve flatulence/carminative in children over 2 years of age
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia
Traditionally used in Western herbal medicine to decrease/reduce/relieve symptoms of indigestion/dyspepsia in children over 2 years of age
Traditionally used in Western herbal medicine to relieve digestive discomfort
Traditionally used in Western herbal medicine to relieve digestive discomfort in children over 2 years of age

Indication Requirements

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

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

Contains ethanol or contains alcohol.
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	Oral Liquid
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Route of Administration Oral

Visual Identification

Active Ingredients

Melissa officinalis herb top Extract liquid	.9 mL/mL
Equivalent: Melissa officinalis (Fresh)	450 mg/mL

Other Ingredients (Excipients)

glycerol

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