



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	308218	FloraMyces
ARTG entry for	Medicine Listed	
Sponsor	Designs For Health Pty Ltd	
Postal Address	1 / 418 Pittwater Road, North Manly, NSW, 2100 Australia	
ARTG Start Date	14/08/2018	
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 . FloraMyces

Product Type	Single Medicine Product	Effective Date	26/06/2020
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Permitted Indications

- Decrease/reduce/relieve diarrhoea
- Helps reduce occurrence of symptoms of traveller's diarrhoea when travelling
- Maintain/support healthy digestive system function
- Maintain/support intestinal good/beneficial/friendly flora
- Helps maintain/support good/beneficial/friendly gut flora during antibiotic use
- Helps maintain/support good/beneficial/friendly gut flora during antibiotic use in children

Indication Requirements

Label statement: Seek medical advice if diarrhoea persists for more than: 6 hours in infants under 6 months, 12 hours in children under 3 years, 24 hours in children aged 3 to 6 years or 48 hours in adults and children over 6 years (or words to that effect).

Standard Indications

No Standard Indications included on Record

Specific Indications

No Specific Indications included on Record

Warnings

No Warnings included on Record

Additional Product information

Pack Size/Poison information

Pack Size	Poison Schedule
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Components

Public Summary



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1 . Formulation 1

Dosage Form Capsule, hard

Route of Administration Oral

Visual Identification

Active Ingredients

Saccharomyces cerevisiae (Boulardii) 500 mg

Other Ingredients (Excipients)

disodium edetate
gellan gum
hypromellose
potable water
potassium acetate

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