



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	399066	Faecal microbiota transplant - BiomeBank
ARTG entry for	Biological Included Class 2	
Sponsor	BiomeBank	
Postal Address	East Wing Level 1 2 Ann Nelson Drive, Thebarton, SA, 5031 Australia	
ARTG Start Date	9/11/2022	
Product Category	Included Class 2	
Status	Active	
Approval Area	Biologicals	

Products

1 . Faecal microbiota, frozen - L - BIOMICTRA

Product Type	Faecal microbiota transplant	Effective Date	20/02/2023
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Intended Use Restoration of gut microbiota in the management of gastrointestinal disorders

Specific Conditions

- Product must only be provided for use by a medical practitioner registered in an Australian State or Territory, under the supervision or on the advice of a specialist gastroenterologist or infectious diseases physician: and
- Product must not be released for use in conditions other than C. difficile infection, unless as part of a registered clinical trial.

Components

1 . Component Description

Dosage Form	Suspension
Route of Administration	Rectal Intraduodenal Intraintestinal

Visual Identification

Active Ingredients

Faecal microbiota	12.5 g
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Other Ingredients (Excipients)

glycerol
sodium chloride
water for injections

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