



Australian Government
Department of Health and Aged Care
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 194957 MUTAFLO[®] Escherichia coli strain Nissle 1917 not less than 250 million CFU enteric, capsule blister pack

ARTG entry for Medicine Registered
Sponsor Prinz Herget Pty Ltd T/A Natural Therapy Imports
Postal Address PO Box 7302, WEST LAKES, SA, 5021
 Australia
ARTG Start Date 28/02/2012
Product Category Medicine
Status Active
Approval Area Registered Complementary Medicines

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1 . MUTAFLO[®] Escherichia coli strain Nissle 1917 not less than 250 million CFU enteric, capsule blister pack

Product Type	Single Medicine Product	Effective Date	28/02/2012
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

For the relief and management of chronic constipation..Increases the number of bowel movements per day and the number of days on which bowel movements occur in patients with chronic constipation.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Blister Pack	Not recorded	12 Months	Store at 2 to 8 degrees Celsius	Not recorded	Do not Freeze Refrigerate

Pack Size/Poison information

Pack Size	Poison Schedule
10	Not scheduled. Not considered by committee
100	Not scheduled. Not considered by committee
20	Not scheduled. Not considered by committee
50	Not scheduled. Not considered by committee

Components

1 .

Dosage Form Capsule, enteric
Route of Administration Oral
Visual Identification Colourless, transparent, oblong hard capsule coated with a reddish-brown enteric coating. The fill is a light beige powder.

Active Ingredients

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Escherichia coli strain Nissle 1917

.25 billion CFU

Other Ingredients (Excipients)

Carnauba Wax
Gelatin
glycerol
iron oxide red
macrogol 4000
maltodextrin
methacrylic acid copolymer
potable water
purified talc
Shellac
sodium lauryl sulfate
titanium dioxide
triethyl citrate
white beeswax

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