



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

## Public Summary

**Summary for ARTG Entry:** 194957 MUTAFLO<sup>®</sup> 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<sup>®</sup> Escherichia coli strain Nissle 1917 not less than 250 million CFU enteric, capsule blister pack

<b>Product Type</b>	Single Medicine Product	<b>Effective Date</b>	28/02/2012
---------------------	-------------------------	-----------------------	------------

#### 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	Refrigerate Do not Freeze

#### 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 .

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

#### Active Ingredients

Public Summary



**Australian Government**  
**Department of Health**  
Therapeutic Goods Administration

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

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary