Public Summary

Summary for ARTG Entry:	90749 GENRX LACTULOSE solution 0.68g/mL bottle
ARTG entry for	Medicine Registered
Sponsor	Apotex Pty Ltd
Postal Address	PO Box 280, NORTH RYDE BC, NSW, 1670 Australia
ARTG Start Date	27/08/2002
Product Category	Medicine
Status	Active
Approval Area	Non-Prescription 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 . GENRX LACTULOSE solution 0.68g/mL bottle

Product Type	Single Medicine Product	**Effective Date**	25/11/2009

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

Treatment of habitual and chronic constipation. Treatment of portal systemic encephalopathy (PSE), hepatic coma and pre-coma.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bottle	HDPE	2 Years	Store below 25 degrees Celsius	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
500mL	Not scheduled. Not considered by committee

Components

1 .

Dosage Form	Solution
Route of Administration	Oral
Visual Identification	A COLOURLESS TO YELLOW CLEAR AQUEOUS SYRUP.

Active Ingredients

lactulose	**.68 g/mL**

Other Ingredients (Excipients)

purified water

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