

Australian Government

Department of Health and Aged Care

Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 146795 FLEET READY-TO-USE ENEMA (reformulation) bottle

ARTG entry for Medicine Registered

Sponsor Care Pharmaceuticals Pty Ltd

Postal Address PO Box 1674, BONDI JUNCTION, NSW, 1355

Australia

ARTG Start Date 29/10/2007
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. FLEET READY-TO-USE ENEMA (reformulation) bottle

Product Type Single Medicine Product Effective Date 2/06/2021

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 relief of constipation only when used under medical supervision. Bowel cleansing before rectal examinations. Fur use as part of a bowel cleansing regimen in preparing the patient for surgery or for preparing the colon for x-ray or endoscopic examination.

Warnings

No Warnings included on Record

Additional Product information

Container information

Туре	Material	Life Time	Temperature	Closure	Conditions
Bottle	LDPE	3 Years	Store below 30	Not recorded	Not recorded

degrees Celsius

Pack Size/Poison information

Pack Size Poison Schedule

133mL Not scheduled. Not considered by committee

Components

1.

Dosage FormEnemaRoute of AdministrationRectal

Visual Identification Clear, colourless solution free from precipitation and turbidity.

Active Ingredients

dibasic sodium phosphate heptahydrate59.3 mg/mLmonobasic sodium phosphate161 mg/mL

Other Ingredients (Excipients)

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benzalkonium chloride disodium edetate purified water

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