COMFORTLAX - polyethylene glycol 3350 powder, for solution Family Dollar Stores, LLC

Polyethylene Glycol 3350 Powder for Oral Solution

Drug Facts

Active ingredient (in each dose)

Polyethylene Glycol 3350, USP 17 grams (cup filled to the indicated 17 grams line)

Purpose

Osmotic Laxative

Use

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 1 to 3 days

Warnings

Allergy alert: Do not use if you are allergic to polyethylene glycol

Do not use if you have kidney disease, except under the advice and supervision of a doctor

Ask a doctor before use if you have

- nausea, vomiting or abdominal pain
- a sudden change in bowel habits that lasts over 2 weeks
- irritable bowel syndrome

Ask a doctor or pharmacist before use if you are taking a prescription drug When using this product you may have loose, watery, more frequent stools

Stop use and ask a doctor if

- you have rectal bleeding or your nausea, bloating, cramping or abdominal pain gets worse. These may be signs of a serious condition.
- you get diarrhea
- you need to use a laxative for longer than 1 week

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children.

In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.

Directions

- do not take more than directed unless advised by your doctor
- this product is supplied with a dosing cup marked to contain 17 grams of powder when filled to the indicated line
- adults and children 17 years of age and older:
 - use once a day
 - fill to the indicated 17 grams line on cup which is marked to indicate the correct dose 17 grams
 - stir and dissolve in any 4 to 8 ounces of beverage (cold, hot or room temperature) then drink
 - do not combine with starch-based thickeners used for difficulty swallowing
 - ensure that the powder is fully dissolved before drinking
 - do not drink if there are any clumps
 - do not use no more than 7 days
- children 16 years of age or under: ask a doctor

Other information

- store at 20° to 25°C (68° to 77°F)
- tamper-evident: do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken

Inactive ingredients

none

Questions or comments?

call **1-855-274-4122**

DISTRIBUTED BY:

MIDWOOD BRANDS, LLC 500 VOLVO PKWY CHESAPEAKE, VA 23320 USA

MADE IN INDIA

Code: TS/DRUGS/16/2014

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 119 g Bottle Label

FAMILY WellnessTM

COMPARE TO THE ACTIVE

INGREDIENT OF MIRALAX®*

COMFORTLAX® Polyethylene Glycol 3350 **Powder for Oral Solution Osmotic Laxative**

UNFLAVORED **POWDER -GRIT FREE**

- Relieves Occasional Constipation/Irregularity
- Softens Stool

7 ONCE-DAILY DOSES **NET WT 4.1 OZ (119 g)**

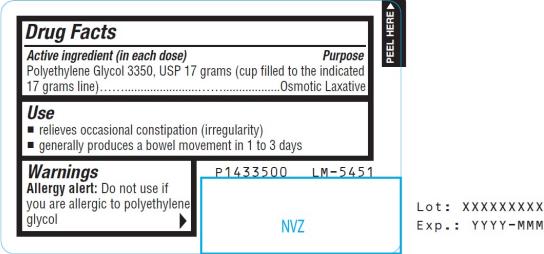
NDC 55319-056-24

Front Label



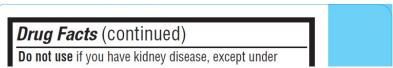
Back Label

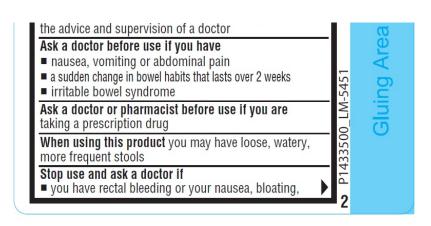
Top Layer Printing side



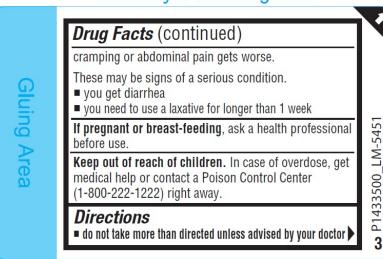
Exp.: YYYY-MMM

Top Layer Adhesive side





2nd Layer Printing side



2nd Layer Adhesive side

Drug Facts (continued)

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Sluing Area

Base Layer

Drug Facts (continued)

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Other information

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COMFORTLAX

polyethylene glycol 3350 powder, for solution

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Product Type HUMAN OTC DRUG Item Code (Source) NDC:55319-056

Route of Administration ORAL

Active Ingredient/Active Moiety

Ingredient Name Basis of Strength Strength

P1433500_LM-545

5

POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL

3350 - UNII:G2M7P15E5P)

POLYETHYLENE 17 g GLYCOL 3350 in 17 g

Product Characteristics

Color	WHITE	Score
Shape		Size
Flavor		Imprint Code
Contains		

Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55319- 056-24	119 g in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package	09/04/2024	
2	NDC:55319- 056-33	238 g in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package	09/04/2024	
3	NDC:55319- 056-27	510 g in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package	09/04/2024	

Marketing Information				
	Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
	ANDA	ANDA209017	09/04/2024	

Labeler - Family Dollar Stores, LLC (024472631)

Registrant - Aurohealth LLC (078728447)

Establishment			
Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(55319-056), MANUFACTURE(55319-056)

Establishment			
Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(55319-056), MANUFACTURE(55319-056)

Revised: 10/2024 Family Dollar Stores, LLC