

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

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**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**  
**Wellness™**

**COMPARE TO THE ACTIVE**

# INGREDIENT OF MIRALAX®\*

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

- Relieves Occasional Constipation/Irregularity
- Softens Stool

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

**UNFLAVORED**  
**POWDER -**  
**GRIT FREE**

**NDC 55319-056-24**

Front Label



Back Label

Top Layer Printing side

<b>Drug Facts</b>	
<b>Active ingredient (in each dose)</b>	<b>Purpose</b>
Polyethylene Glycol 3350, USP 17 grams (cup filled to the indicated 17 grams line).....	Osmotic Laxative
<b>Use</b>	
■ relieves occasional constipation (irregularity)	
■ generally produces a bowel movement in 1 to 3 days	
<b>Warnings</b>	P1433500 LM-5451
<b>Allergy alert:</b> Do not use if you are allergic to polyethylene glycol	Lot: XXXXXXXXX Exp.: YYYY-MMM

PEEL HERE

NVZ

Top Layer Adhesive side

<b>Drug Facts (continued)</b>
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, ▶

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Gluing Area

## 2nd Layer Printing side

Gluing Area

**Drug Facts** (continued)

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 ▶

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## 2nd Layer Adhesive side

**Drug Facts** (continued)

- 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 ▶

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Gluing Area

## Base Layer

Gluing Area

**Drug Facts** (continued)

- do not use 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)

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■ 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

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**COMFORTLAX**

polyethylene glycol 3350 powder, for solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:55319-056
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	17 g in 17 g

**Product Characteristics**

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**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**

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

**Establishment**

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

Revised: 10/2024

Family Dollar Stores, LLC