

POLYETHYLENE GLYCOL 3350 - polyethylene glycol 3350 powder, for solution
LEADER/ CARDINAL HEALTH 110, INC.

Polyethylene Glycol 3350 Powder for Oral Solution

Drug Facts

Active ingredient (in each dose)

Polyethylene Glycol 3350, USP 17 grams

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**
- adults and children 17 years of age and older:
 - use once a day
 - stir and dissolve one packet of powder (17 g) 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 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 is open or broken

Inactive ingredients

none

Questions or comments?

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

DISTRIBUTED BY
CARDINAL HEALTH
DUBLIN, OHIO 43017
www.myleader.com 1-800-200-6313
Essential to Care™ since 1979

Made in India

Code: TS/DRUGS/16/2014

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 17 g Pouch Label

LEADER™

NDC 70000-0699-1

Grit-Free | Unflavored Powder Packet
Polyethylene
Glycol 3350
Powder for Oral Solution

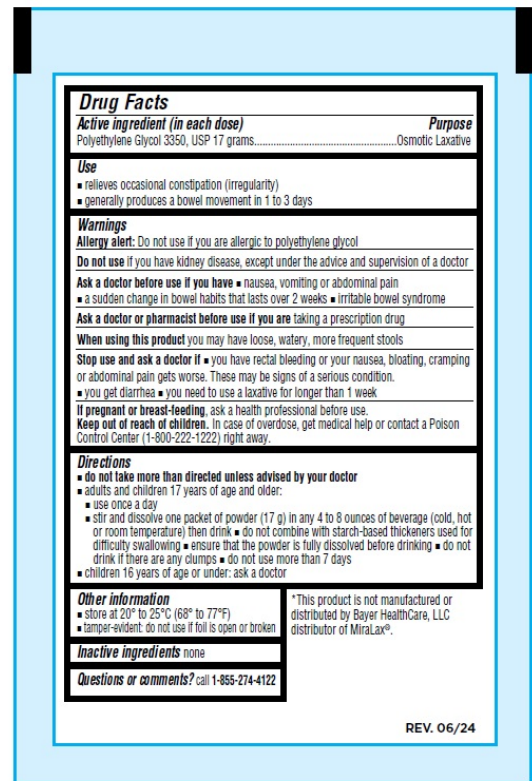
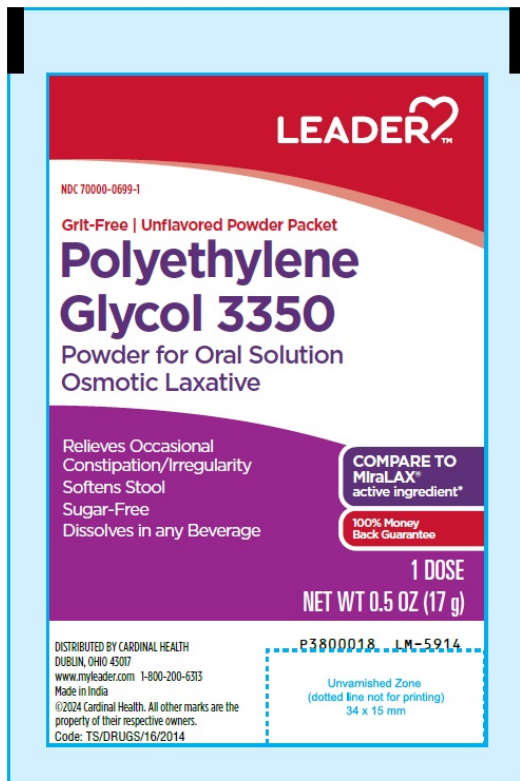
Osmotic Laxative

Relieves Occasional
Constipation/Irregularity
Softens Stool
Sugar-Free
Dissolves in any Beverage

**COMPARE TO
MiraLAX®
active ingredient***

**100% Money
Back Guarantee**

**1 DOSE
NET WT 0.5 OZ (17g)**



PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 17 g Pouch Carton Label

LEADER™

NDC 70000-0699-2

**Grit-Free | Unflavored Powder Packets
Polyethylene Glycol 3350
Powder for Oral Solution | Osmotic Laxative**

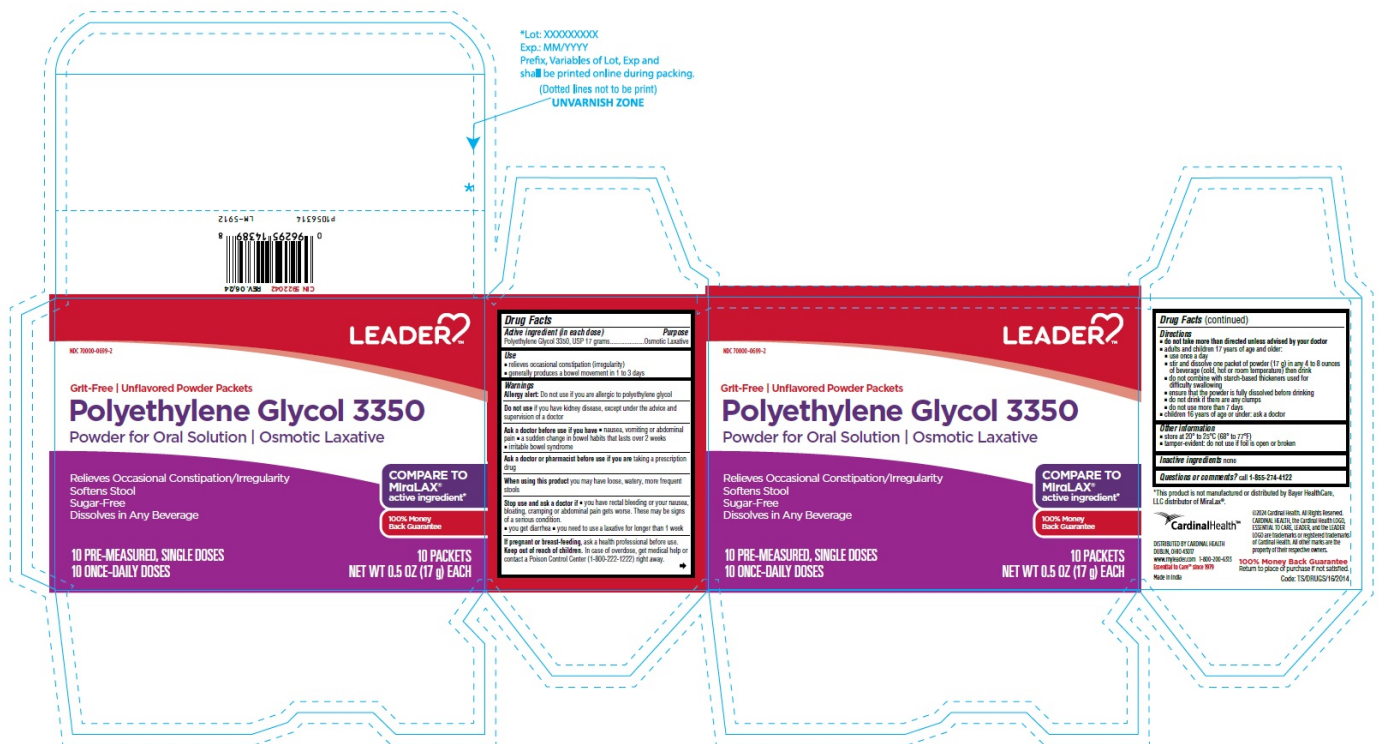
Relieves Occasional Constipation/Irregularity
Softens Stool
Sugar-Free
Dissolves in Any Beverage

**COMPARE TO
MiraLAX®
active ingredient***

**100% Money
Back Guarantee**

**10 PRE-MEASURED, SINGLE DOSES
10 ONCE-DAILY DOSES
(17g) EACH**

**10 PACKETS
NET WT 0.5 OZ**



POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:70000-0699
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
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POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	17 g in 17 g
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Product Characteristics

Color	WHITE	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:70000-0699-2	10 in 1 CARTON	11/08/2024	
1		17 g in 1 PACKET; Type 1: Convenience Kit of Co-Package		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA209017	11/08/2024	

Labeler - LEADER/ CARDINAL HEALTH 110, INC. (063997360)

Registrant - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(70000-0699) , MANUFACTURE(70000-0699)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(70000-0699) , MANUFACTURE(70000-0699)

Revised: 11/2024

LEADER/ CARDINAL HEALTH 110, INC.