

POLYETHYLENE GLYCOL 3350 - polyethylene glycol 3350 powder, for solution
Aurohealth LLC

Polyethylene Glycol 3350 Powder for Oral Solution

Drug Facts

Active ingredient (in each dose)

Polyethylene Glycol 3350, USP 17 g (cap filled to 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**
- the bottle top is a measuring cap marked to contain 17 grams of powder when filled to the indicated line (white section in cap)
- adults and children 17 years of age and older:
 - use once a day
 - fill to top of white section in cap which is marked to indicate the correct dose (17g)
 - 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 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:

AUROHEALTH LLC

279 Princeton-Hightstown Road
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/16/2014

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 119 g Bottle Label

AUROHEALTH

NDC 58602-805-01

**Compare to active ingredient
of MiraLax®***

**Polyethylene Glycol 3350
Powder for Oral Solution**

Osmotic Laxative

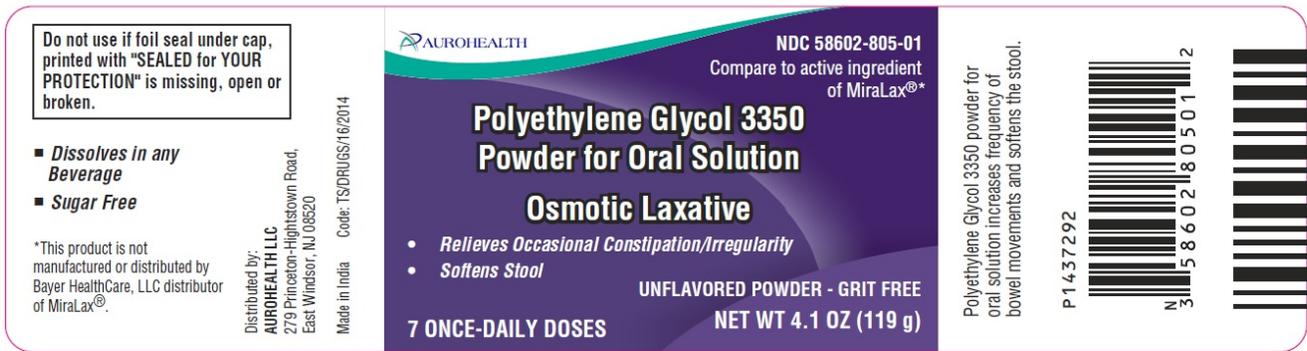
- **Relieves Occasional Constipation/Irregularity**
- **Softens Stool**

UNFLAVORED POWDER - GRIT FREE

7 ONCE-DAILY DOSES

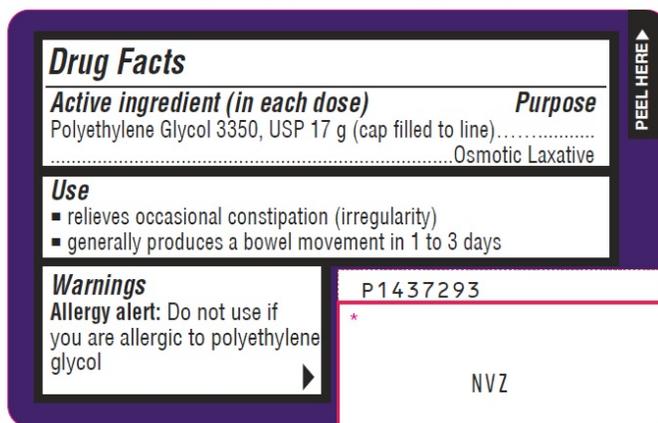
NET WT 4.1 OZ (119 g)

Front Label



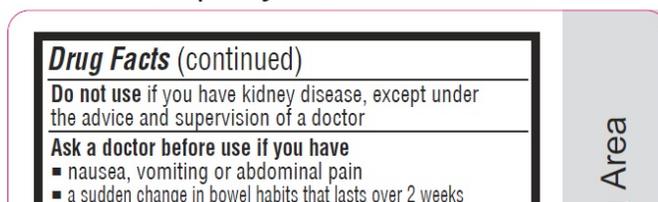
Back Label

Top Layer Printing side



*Lot: XXXXXXXX
Exp.: YYYY-MMM
Prefix, Variables of Lot and Exp
shall be printed online during packing.

Top Layer Adhesive side



<ul style="list-style-type: none"> ▪ irritable bowel syndrome 	P1437293	Gluing
<p>Ask a doctor or pharmacist before use if you are taking a prescription drug</p>		
<p>When using this product you may have loose, watery, more frequent stools</p>		
<p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> ▪ you have rectal bleeding or your nausea, bloating, ▶ 		
2		

2nd Layer Printing side

Gluing Area	<p>Drug Facts (continued)</p> <p>cramping or abdominal pain gets worse. These may be signs of a serious condition.</p> <ul style="list-style-type: none"> ▪ you get diarrhea ▪ you need to use a laxative for longer than 1 week 	P1437293	Gluing
	<p>If pregnant or breast-feeding, ask a health professional before use.</p>		
	<p>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.</p>		
	<p>Directions</p> <ul style="list-style-type: none"> ▪ do not take more than directed unless advised by your doctor ▶ 		
3			

2nd Layer Adhesive side

Gluing Area	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ▪ the bottle top is a measuring cap marked to contain 17 grams of powder when filled to the indicated line (white section in cap) ▪ adults and children 17 years of age and older: <ul style="list-style-type: none"> ▪ use once a day ▪ fill to top of white section in cap which is marked to indicate the correct dose (17g) ▪ 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 	P1437293	Gluing Area	
4				

Base Layer

Gluing Area	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> ▪ do not use more than 7 days ▪ children 16 years of age or under: ask a doctor 	P1437293	Gluing Area
	<p>Other information</p> <ul style="list-style-type: none"> ▪ 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 		
	<p>Inactive ingredients</p> <p>none</p>		
	<p>Questions or comments?</p> <p>call 1-855-274-4122</p>		
5			

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 17 g Sachet Label

AUROHEALTH

NDC 58602-805-26

Compare to active ingredient
of MiraLax®*

**Polyethylene Glycol 3350
Powder for Oral Solution**

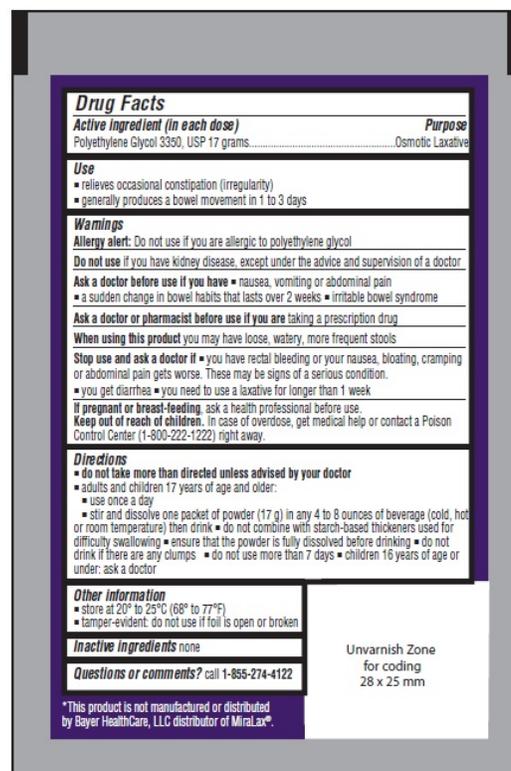
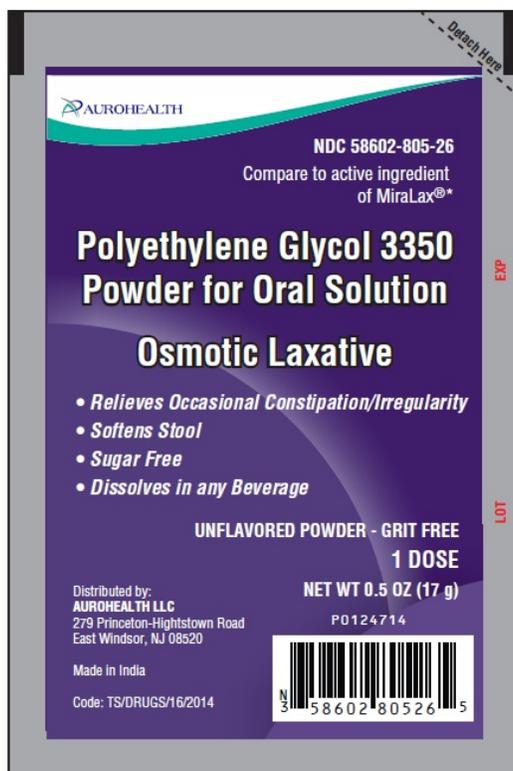
Osmotic Laxative

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

UNFLAVORED POWDER - GRIT FREE

1 DOSE

NET WT 0.5 oz (17 g)



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

AUROHEALTH

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:58602-805
Route of Administration	ORAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	17 g 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:58602-805-01	119 g in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package	04/09/2018	
2	NDC:58602-805-02	238 g in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package	04/09/2018	
3	NDC:58602-805-03	510 g in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package	04/09/2018	
4	NDC:58602-805-04	850 g in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package	04/09/2018	
5	NDC:58602-805-25	765 g in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package	04/23/2024	
6	NDC:58602-805-27	14 in 1 CARTON	04/23/2024	
6		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	04/09/2018	

Labeler - Aurohealth LLC (078728447)

Establishment

Name	Address	ID/FEI	Business Operations
Aurobindo Pharma Limited		918917642	ANALYSIS(58602-805) , MANUFACTURE(58602-805)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(58602-805) , MANUFACTURE(58602-805)

Revised: 9/2025

Aurohealth LLC