

**POLYETHYLENE GLYCOL 3350 - polyethylene glycol 3350 powder, for solution**

**Aurohealth 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:

**AUROHEALTH LLC**

279 Princeton-Hightstown Road  
East Windsor, NJ 08520

Made in India

Code: TS/DRUGS/19/1993

**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)**

## Top Layer

<p>Distributed by: <b>AUROHEALTH LLC</b> 279 Princeton-Hightstown Road East Windsor, NJ 08520</p> <p>Made In India</p> <p>Code: TS/DRUGS/19/1993</p> 	<p><b>AUROHEALTH</b> NDC 58602-905-01</p> <p>Compare to active ingredient of MiraLax®*</p> <h3>Polyethylene Glycol 3350 Powder for Oral Solution</h3> <h3>Osmotic Laxative</h3> <ul style="list-style-type: none"> <li>Relieves Occasional Constipation/Irregularity</li> <li>Softens Stool</li> </ul> <p>UNFLAVORED POWDER - GRIT FREE</p> <p>7 ONCE-DAILY DOSES NET WT 4.1 OZ (119 g)</p>	<p style="text-align: right;"><b>LIFT HERE for Drug Facts</b></p> <div style="border: 1px solid black; padding: 5px; margin-bottom: 10px;"> <p><b>Do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken.</b></p> </div> <p>Polyethylene Glycol 3350 powder for oral solution increases frequency of bowel movements and softens the stool.</p> <ul style="list-style-type: none"> <li>• <i>Dissolves In any Beverage</i></li> <li>• <i>Sugar Free</i></li> </ul> <p>*This product is not manufactured or distributed by Bayer HealthCare, LLC distributor of MiraLax®.</p> <p style="text-align: center;">P1428398</p> <p>Batch: _____</p> <p>Expiry: _____</p>
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Unvarnished Zone  
(dotted line not for printing)

## Top Layer Back side (Adhesive Side)

<p><b>Drug Facts</b></p> <p><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</p> <p><b>Use</b></p> <ul style="list-style-type: none"> <li>• relieves occasional constipation (irregularity)</li> <li>• generally produces a bowel movement in 1 to 3 days</li> </ul> <p><b>Warnings</b></p> <p><b>Allergy alert:</b> Do not use if you are allergic to polyethylene glycol</p> <p><b>Do not use</b> if you have kidney disease, except under the advice and supervision of a doctor</p> <p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>• nausea, vomiting or abdominal pain</li> <li>• a sudden change in bowel habits that lasts over 2 weeks</li> <li>• irritable bowel syndrome</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are taking a prescription drug</b></p>	<p><b>Drug Facts (continued)</b></p> <p><b>When using this product</b> you may have loose, watery, more frequent stools</p> <p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>• you have rectal bleeding or your nausea, bloating, cramping or abdominal pain gets worse. These may be signs of a serious condition.</li> <li>• you get diarrhea</li> <li>• you need to use a laxative for longer than 1 week</li> </ul> <p><b>If pregnant or breast-feeding,</b> ask a health professional before use.</p> <p><b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center (1-800-222-1222) right away.</p> <p><b>Directions</b></p> <ul style="list-style-type: none"> <li>• do not take more than directed unless advised by your doctor</li> <li>• this product is supplied with a dosing cup marked to contain 17 grams of powder when filled to the indicated line</li> </ul>
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## Base layer

<p><b>AUROHEALTH</b> NDC 58602-905-01</p> <p>Compare to active ingredient of MiraLax®*</p> <h3>Polyethylene Glycol 3350 Powder for Oral Solution</h3> <h3>Osmotic Laxative</h3> <ul style="list-style-type: none"> <li>Relieves Occasional Constipation/Irregularity</li> <li>Softens Stool</li> </ul> <p>UNFLAVORED POWDER - GRIT FREE</p> <p>7 ONCE-DAILY DOSES NET WT 4.1 OZ (119 g)</p>	<p><b>Drug Facts (continued)</b></p> <ul style="list-style-type: none"> <li>• adults and children 17 years of age and older:             <ul style="list-style-type: none"> <li>• use once a day</li> <li>• fill to the indicated 17 grams line on cup which is marked to indicate the correct dose 17 grams</li> <li>• stir and dissolve in any 4 to 8 ounces of beverage (cold, hot or room temperature) then drink</li> <li>• do not combine with starch-based thickeners used for difficulty swallowing</li> <li>• ensure that the powder is fully dissolved before drinking</li> <li>• do not drink if there are any clumps</li> <li>• do not use more than 7 days</li> <li>• children 16 years of age or under: ask a doctor</li> </ul> </li> </ul> <p><b>Other information</b></p> <ul style="list-style-type: none"> <li>• store at 20° to 25°C (68° to 77°F)</li> <li>• tamper-evident: do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken</li> </ul> <p><b>Inactive ingredients</b> none</p> <p><b>Questions or comments?</b> call 1-855-274-4122</p>
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# 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**

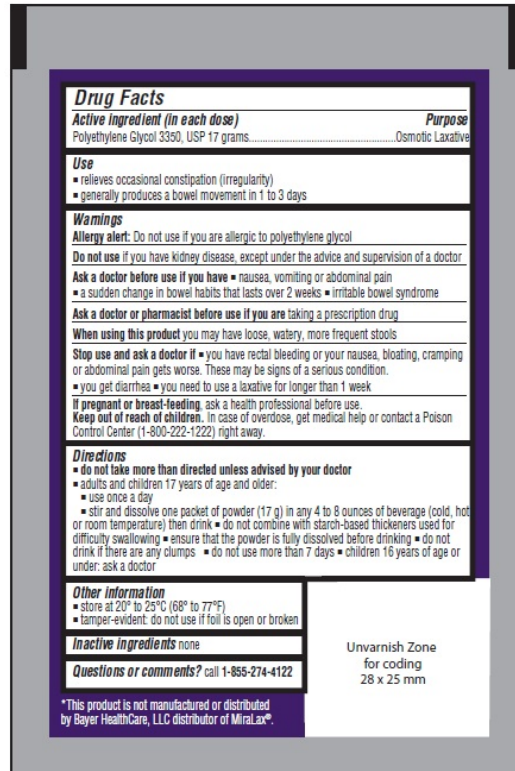
**Osmotic Laxative**

- **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

NDC 58602-805-27

Compare to active ingredient  
of MiraLax®\*

## Polyethylene Glycol 3350 Powder for Oral Solution

### Osmotic Laxative

Polyethylene Glycol 3350 powder for oral solution increases frequency of bowel movements and softness the stool.

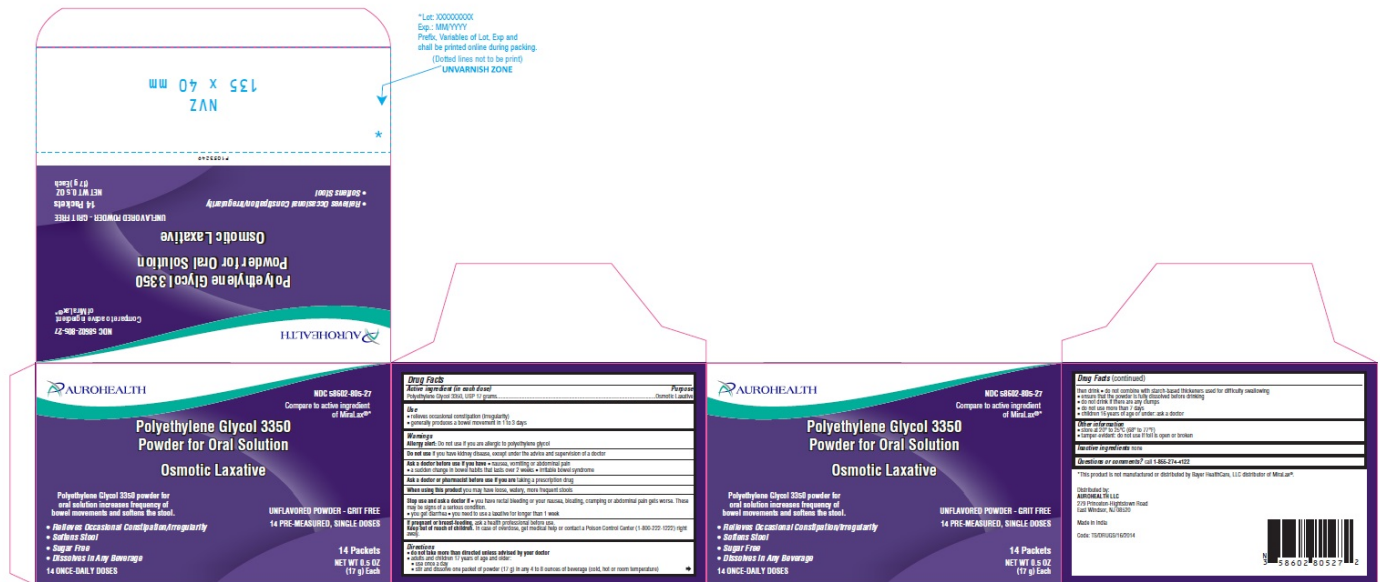
- **Relieves Occasional Constipation/Irregularity**
- **Softens Stool**
- **Sugar Free**
- **Dissolves in Any Beverage**

14 ONCE-DAILY DOSES

UNFLAVORED POWDER - GRIT FREE

14 PRE-MEASURED, SINGLE DOSES

14 Packets  
NET WT 0.5 oz  
(17 g) Each



**POLYETHYLENE GLYCOL 3350**  
polyethylene glycol 3350 powder, for solution

## Product Information

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

## Active Ingredient/Active Moiety

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<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: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

<b>Marketing Category</b>	<b>Application Number or Monograph Citation</b>	<b>Marketing Start Date</b>	<b>Marketing End Date</b>
ANDA	ANDA209017	04/09/2018	

**Labeler** - Aurohealth LLC (078728447)

## Establishment

<b>Name</b>	<b>Address</b>	<b>ID/FEI</b>	<b>Business Operations</b>
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: 4/2024

Aurohealth LLC