

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 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**

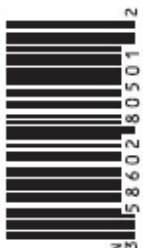
Osmotic Laxative

- *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: AUROHEALTH LLC 279 Princeton-Hightstown Road East Windsor, NJ 08520</p> <p>Made In India</p> <p>Code: TS/DRUGS/19/1993</p> 	<p>AUROHEALTH</p> <p>NDC 58602-805-01</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"> Relieves Occasional Constipation/Irregularity Softens Stool <p>UNFLAVORED POWDER - GRIT FREE</p> <p>7 ONCE-DAILY DOSES NET WT 4.1 OZ (119 g)</p>	<p>LIFT HERE for Drug Facts</p> <div style="border: 1px solid black; padding: 5px;"> <p>Do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken.</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"> Dissolves In any Beverage Sugar Free <p>*This product is not manufactured or distributed by Bayer HealthCare, LLC distributor of MiraLax®.</p> <p>P 1428398</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>Drug Facts</p> <p>Active ingredient (in each dose) Purpose Polyethylene Glycol 3350, USP 17 grams (cup filled to the Indicated 17 grams line).....Osmotic Laxative</p> <p>Use</p> <ul style="list-style-type: none"> relieves occasional constipation (irregularity) generally produces a bowel movement in 1 to 3 days <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to polyethylene glycol</p> <p>Do not use if you have kidney disease, except under the advice and supervision of a doctor</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> nausea, vomiting or abdominal pain a sudden change in bowel habits that lasts over 2 weeks irritable bowel syndrome <p>Ask a doctor or pharmacist before use if you are taking a prescription drug</p>	<p>Drug Facts (continued)</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, 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 <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 this product is supplied with a dosing cup marked to contain 17 grams of powder when filled to the Indicated line
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Base layer

<p>AUROHEALTH</p> <p>NDC 58602-805-01</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"> Relieves Occasional Constipation/Irregularity Softens Stool <p>UNFLAVORED POWDER - GRIT FREE</p> <p>7 ONCE-DAILY DOSES NET WT 4.1 OZ (119 g)</p>	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> adults and children 17 years of age and older: <ul style="list-style-type: none"> 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 more than 7 days children 16 years of age or under: ask a doctor <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 none</p> <p>Questions or comments? call 1-855-274-4122</p>
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POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

Product Information

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	

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)