

POLYETHYLENE GLYCOL 3350 - polyethylene glycol 3350 powder, for solution

Aurobindo Pharma Limited

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:

Aurobindo Pharma USA, Inc.
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

AUROBINDO

NDC 84386-125-08

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

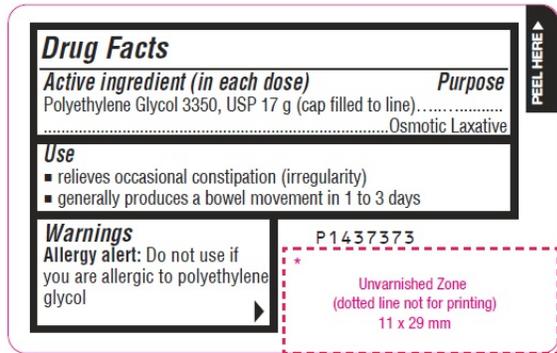
7 ONCE-DAILY DOSES NET WT 4.1 OZ (119 g)

Front Label



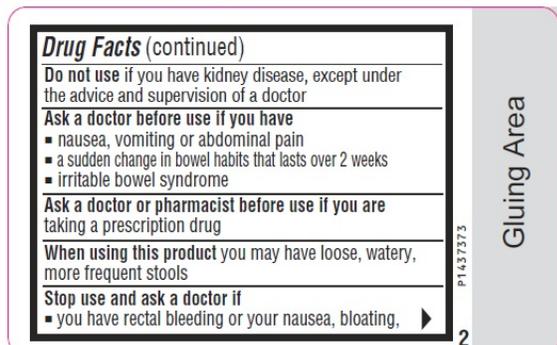
Back Label

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



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
- the bottle top is a measuring cap marked to contain

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2nd Layer Adhesive side

Drug Facts (continued)

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

Gluing Area

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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)
- 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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Labeling Format Information:	
Font type :	Helvetica Condensed
Barline	2.5 pt
Hairline	0.5 pt
Drug facts :	9 pt
Drug facts (continued):	8 pt
Header :	7 pt
Subheader :	6 pt
Leading :	0.5 pt
Body text :	6 pt
Bullets :	5 pt

PACKAGE LABEL-PRINCIPAL DISPLAY PANEL - 17 g Sachet Label

Compare to active ingredient
of MiraLax®*

**Polyethylene Glycol 3350
Powder for Oral Solution**

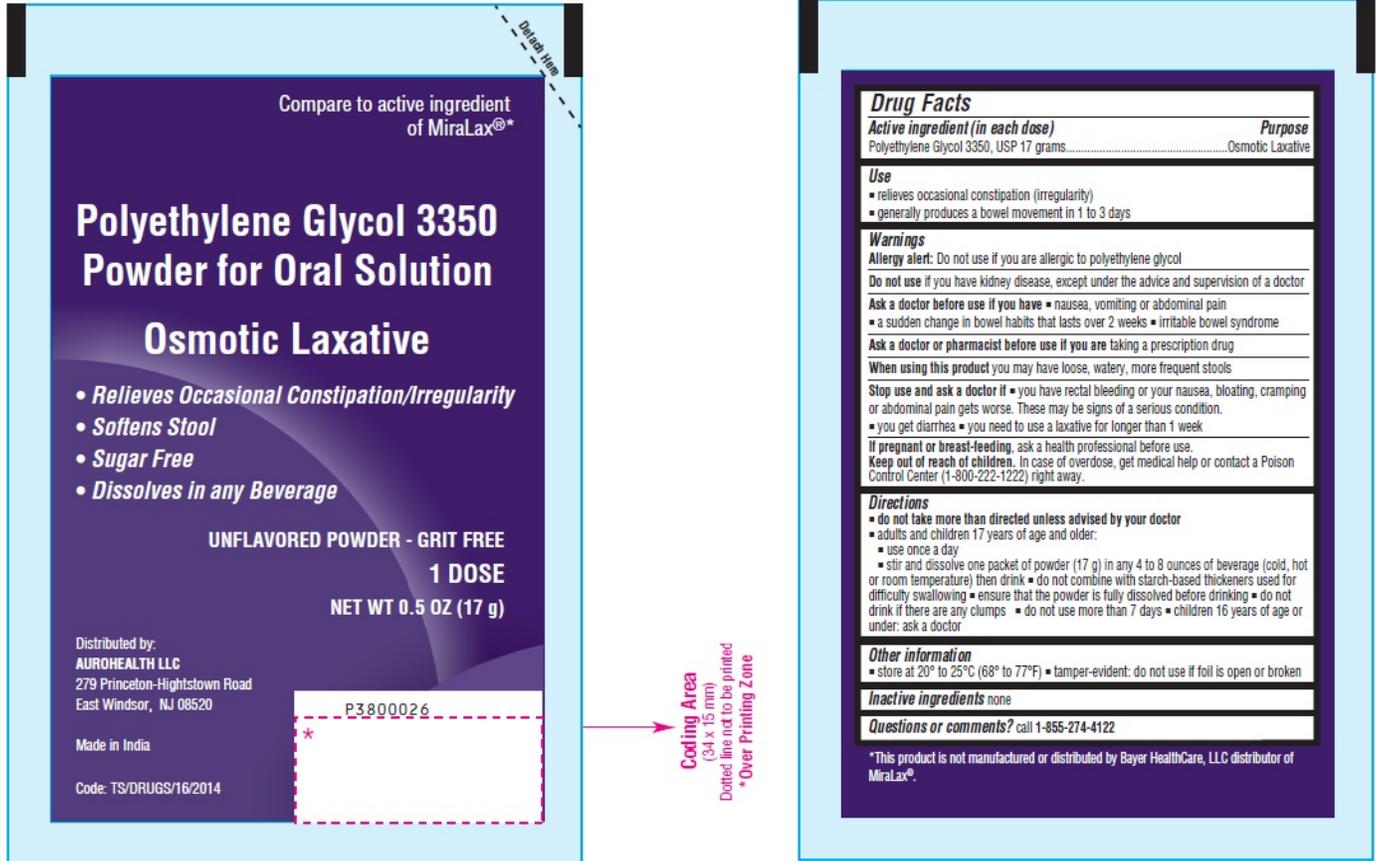
Osmotic Laxative

- **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

AUROBINDO

NDC 84386-125-14

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 softens the stool.

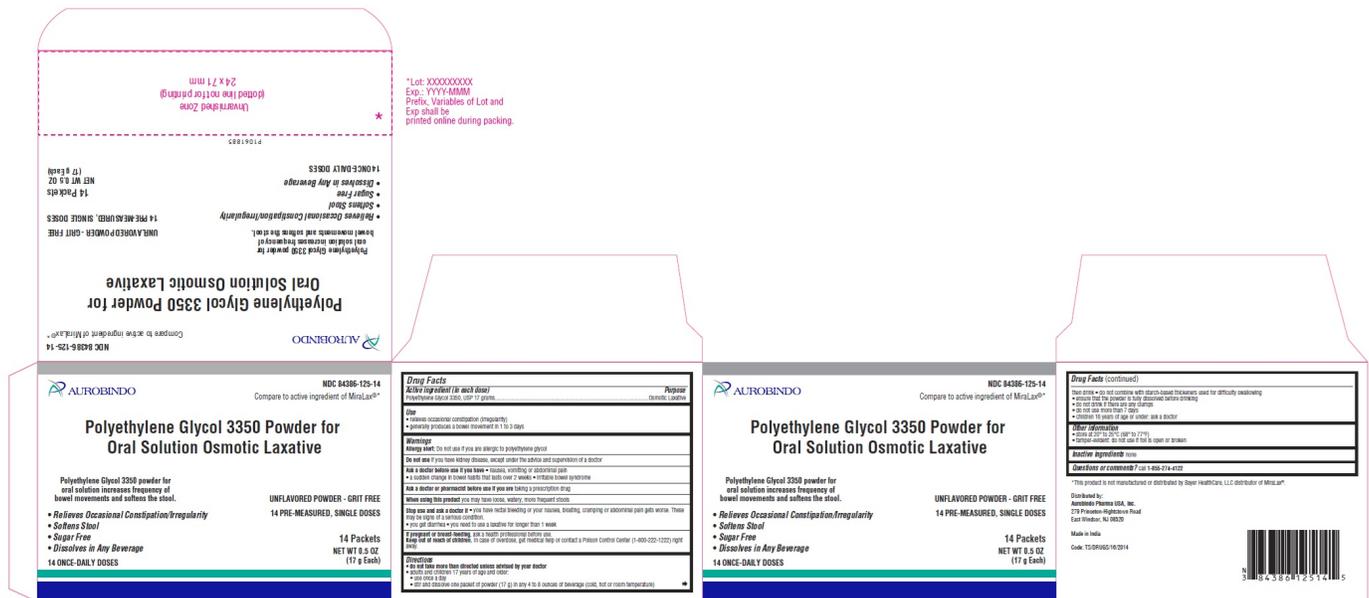
- **Relieves Occasional Constipation/Irregularity**
- **Softens Stool**
- **Sugar Free**
- **Dissolves in Any Beverage**

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

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:84386-125
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:84386-125-08	119 g in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package	01/07/2026	
2	NDC:84386-125-24	238 g in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package	01/07/2026	
3	NDC:84386-125-54	510 g in 1 BOTTLE, PLASTIC; Type 1: Convenience Kit of Co-Package	01/07/2026	
4	NDC:84386-125-14	14 in 1 CARTON	01/07/2026	
4		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	01/07/2026	

Labeler - Aurobindo Pharma Limited (650082092)

Establishment

Name	Address	ID/FEI	Business Operations
APL HEALTHCARE LIMITED		650844777	ANALYSIS(84386-125) , MANUFACTURE(84386-125)

Revised: 1/2026

Aurobindo Pharma Limited