

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

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**Polyethylene Glycol 3350 Powder for Oral Solution, 17 g**

**ACTIVE INGREDIENT (IN EACH DOSE)**

Polyethylene Glycol 3350, 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 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 (17 g)
  - 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 difficult 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?**



**Top Layer**

Polyethylene Glycol 3350 Powder for Oral Solution increases frequency of bowel movements and softens the stool.  
 \*This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of MiraLax®.  
 • **Dissolves in any Beverage**  
 • **Sugar Free**  
 Mfg. Lic. No.: 24/MD/TS/2016/F/G  
 Manufactured by: Annora Pharma Private Limited, Sy. No. 261, Annaram Village, Gummadidala Mandal, Sangareddy District-502313, Telangana, India.  
 For BluePoint Laboratories  
 Rev: 06/2023      2xxxxxx

Peel here

Un varnish area for Batch coding details

680011607551

60 mm

64 mm

**Top Layer Back**

**Drug Facts (continued)**

In case of overdose, get medical help or contact a Poison Control Center 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 (17 g)
  - 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

3

60 mm

64 mm

**Second Layer**

**Drug Facts (continued)**

- 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 1-888-588-1418.

4

60 mm

64 mm

**Labeling Format Information:**

Font type :	Helvetica
Barline	1.5 pt
Hairline	0.5 pt
Drug facts :	9 pt
Drug facts (Continued) :	8 pt
Header :	8 pt
Subheader :	6 pt
Body text :	6 pt
Bullets :	5 pt

Polyethylene glycol 3350 powder for oral solution 510g bottle label

Top Layer

NDC 68001-607-69

Compare to the active ingredient in Miralax®

**Polyethylene Glycol 3350 Powder for Oral Solution Osmotic Laxative**

**17 g/dose**

- Relieves Occasional Constipation/Irregularity
- Softens Stool

Unflavored Powder  
Grit Free

**BluePoint**  
LABORATORIES

30 Once-Daily Doses  
NET WT 17.9 OZ (510 g)

80 mm

85 mm

Top Layer Back

**Drug Facts**

**Active Ingredient (in each dose)**      **Purpose**  
Polyethylene Glycol 3350, 17 g  
(cap filled to line)      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

2x x x x x x      1

80 mm

85 mm

Second Layer

**Drug Facts (continued)**

- 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.

Please see back label for continued Drug Facts      2

80 mm

85 mm

Labeling Format Information:

Font type :	Helvetica
Barline	1.5 pt
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**Top Layer**

**Top Layer Back**

**Second Layer**

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Header :	8 pt
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Top Layer

NDC 68001-607-55

\*Compare to the active ingredient in MiraLax®

**Polyethylene Glycol 3350 Powder for Oral Solution**  
**Osmotic Laxative**

**17 g/dose**

- Relieves Occasional Constipation/Irregularity
- Softens Stool

Unflavored Powder  
Grit Free

14 Once-Daily Doses  
NET WT 8.3 OZ (238 g)

BluePoint LABORATORIES

2103018

60 mm (height)

64 mm (width)

Top Layer Back

**Drug Facts**

**Active ingredient (in each dose) Purpose**  
 Polyethylene Glycol 3350, 17 g (cap filled to line).....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
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1

60 mm (height)

64 mm (width)

Second Layer

**Drug Facts (continued)**

- 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.**

Please see back label for continued Drug Facts

2

60 mm (height)

64 mm (width)

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**Top Layer**

**Top Layer Back**

**Second Layer**

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Top Layer

NDC 68001-607-69

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Without glue dotted line area

\*Compare to the active ingredient in MiraLax™

# Polyethylene Glycol 3350 Powder for Oral Solution

## Osmotic Laxative

**17 g/dose**

- Relieves Occasional Constipation/Irregularity
- Softens Stool

Unflavored Powder  
Grit Free

BluePoint LABORATORIES

30 Once-Daily Doses  
NET WT 17.9 OZ (510 g)

2103017

80 mm

85 mm

Top Layer Back

**Drug Facts**

Active ingredient (in each dose)	Purpose
Polyethylene Glycol 3350, 17 g (cap filled to line)	Osmotic Laxative

**Use**

- relieves occasional constipation (irregularity)
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Second Layer

**Drug Facts (continued)**

- irritable bowel syndrome

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**Keep out of reach of children.**

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Please see back label for continued Drug Facts

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### Top Layer

### Top Layer Back

### Second Layer

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## POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68001-607
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

<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:68001-607-55	238 g in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2023	
2	NDC:68001-607-69	510 g in 1 BOTTLE; Type 0: Not a Combination Product	10/01/2023	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214990	10/01/2023	

**Labeler** - BluePoint Laboratories (985523874)

## Establishment

Name	Address	ID/FEI	Business Operations
Annora Pharma Private Limited		650980746	manufacture(68001-607)

Revised: 1/2024

BluePoint Laboratories