# 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

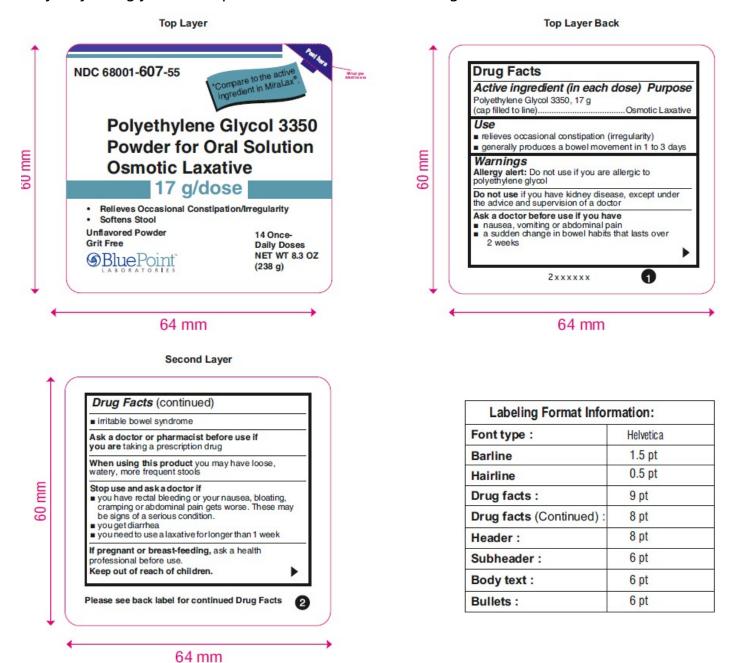
#### **INACTIVE INGREDIENTS**

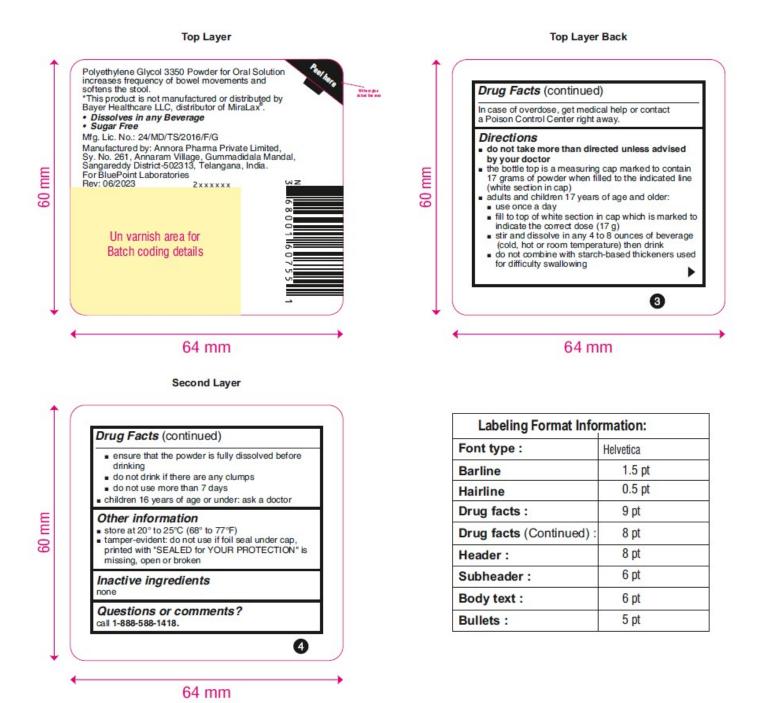
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## **QUESTIONS OR COMMENTS?**

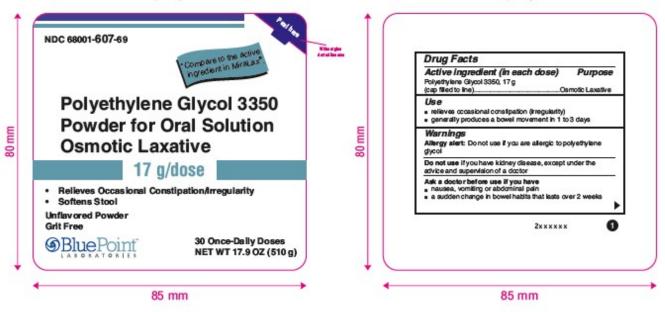
#### PRINCIPAL DISPLAY PANEL

Polyethylene glycol 3350 powder for oral solution 238g bottle label





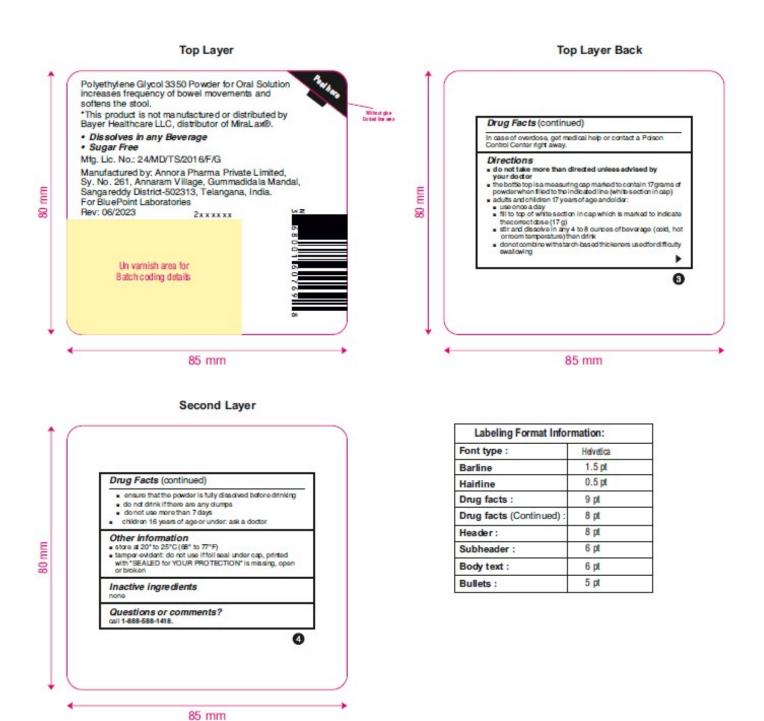
Polyethylene glycol 3350 powder for oral solution 510g bottle label



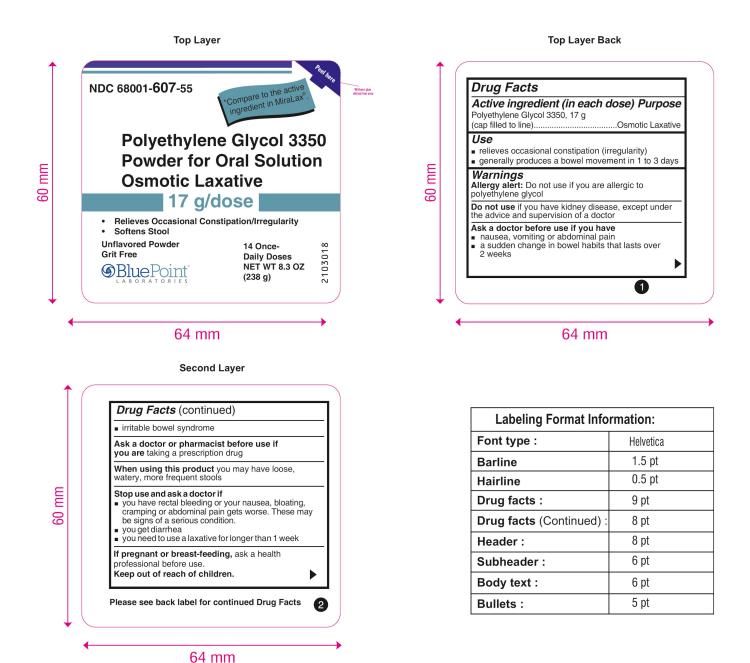
#### Second Layer



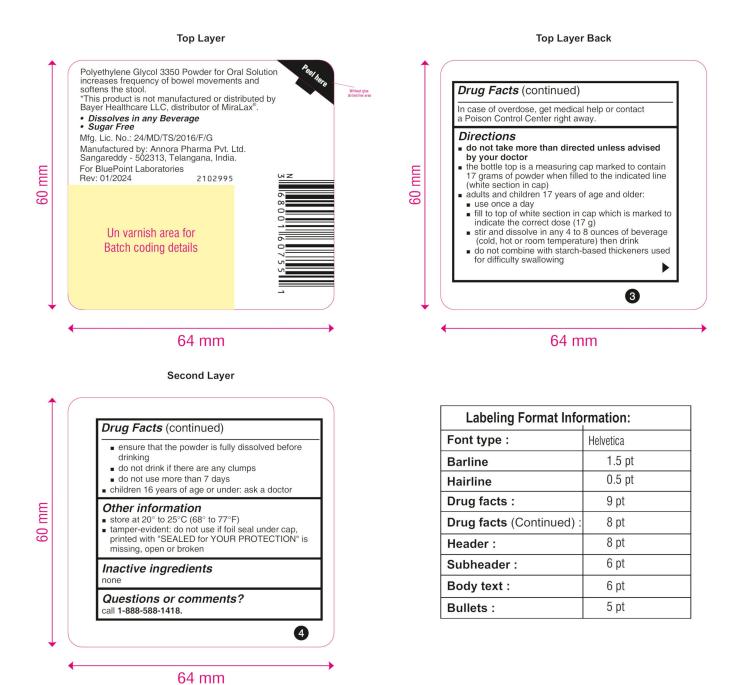
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Hairline	0.5 pt	
Drug facts :	9 pt	
Drug facts (Continued):	8 pt	
Header:	8 pt	
Subheader :	6 pt	
Body text :	6 pt	
Bullets :	5 pt	



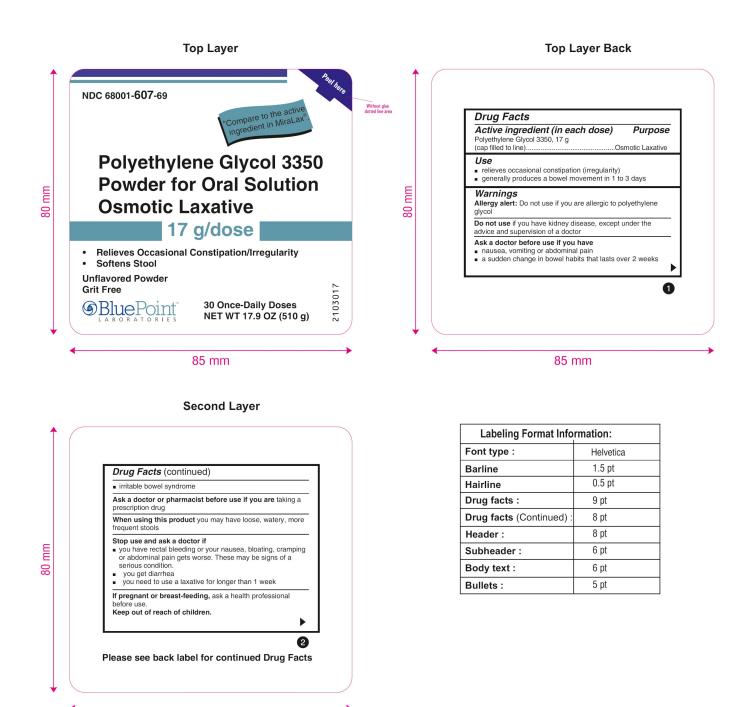
Polythylene Glycol Powder 238g Label Page 1 Rev 012024



Polythylene Glycol Powder 238g Label Page 2 Rev 012024



Polythylene Glycol Powder 510g Label Page 1 Rev 012024



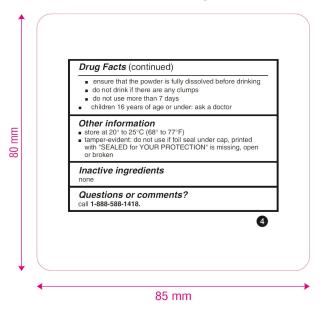
Polythylene Glycol Powder 510g Label Page 2 Rev 012024

85 mm



#### **Second Layer**

85 mm



Labeling Format Information:			
Font type :	Helvetica		
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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		

85 mm

## **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	<b>Basis of Strength</b>	Strength	
<b>POLYETHYLENE GLYCOL 3350</b> (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			

F	Packaging				
#	tem 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	<b>Business Operations</b>	
Annora Pharma Private Limited		650980746	manufacture(68001-607)	

Revised: 1/2024 BluePoint Laboratories