POLYETHYLENE GLYCOL- polyethylene glycol powder, for suspension
BluePoint Laboratories

ACTIVE INGREDIENT

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 THE REACH OF CHILDREN

In case of overdose, get medical help or contact a POISON CONTROL CENTER right away. (1-800-222-1222)

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.
- adults and children 17 years of age and older:
- use once a day
- fill to top of line 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
- 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°- 25°C (68°– 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?

1-866-403-7592

Package Label - Principal Display Panel

NDC: 68001-505-55

Original Prescription Strength

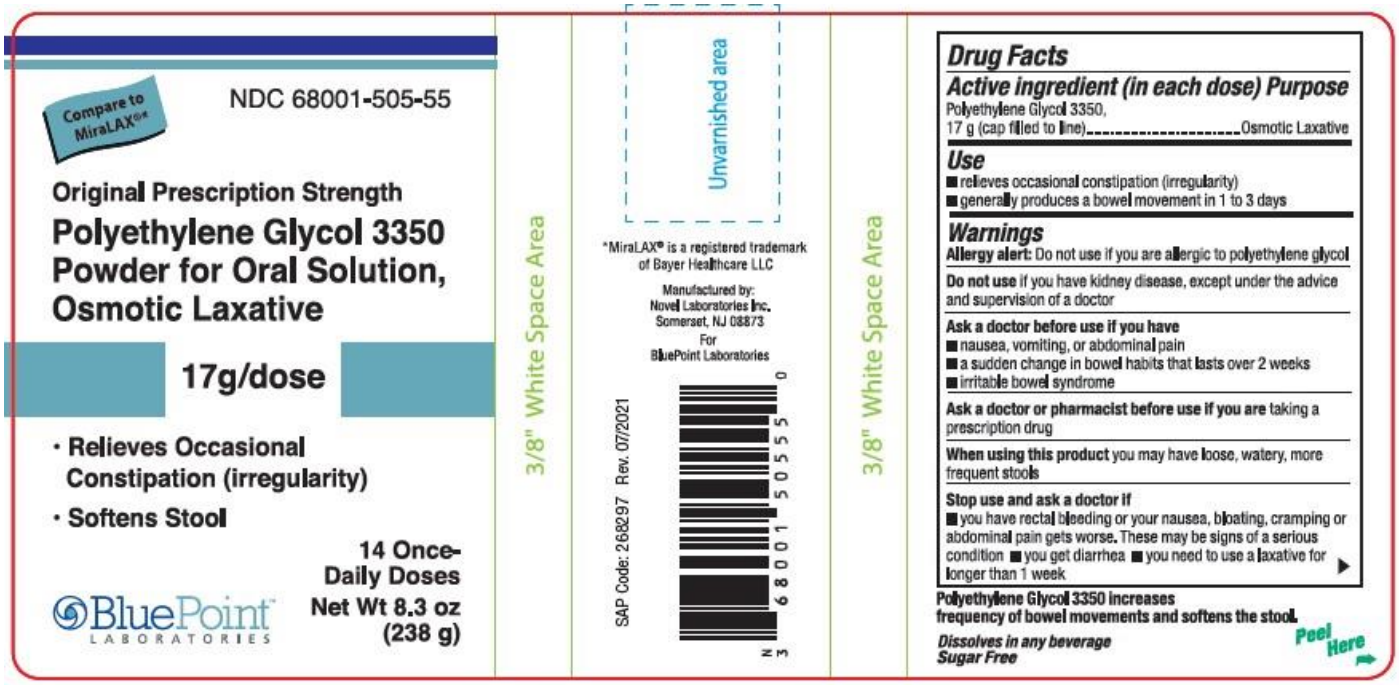
Polyethylene Glycol 3350

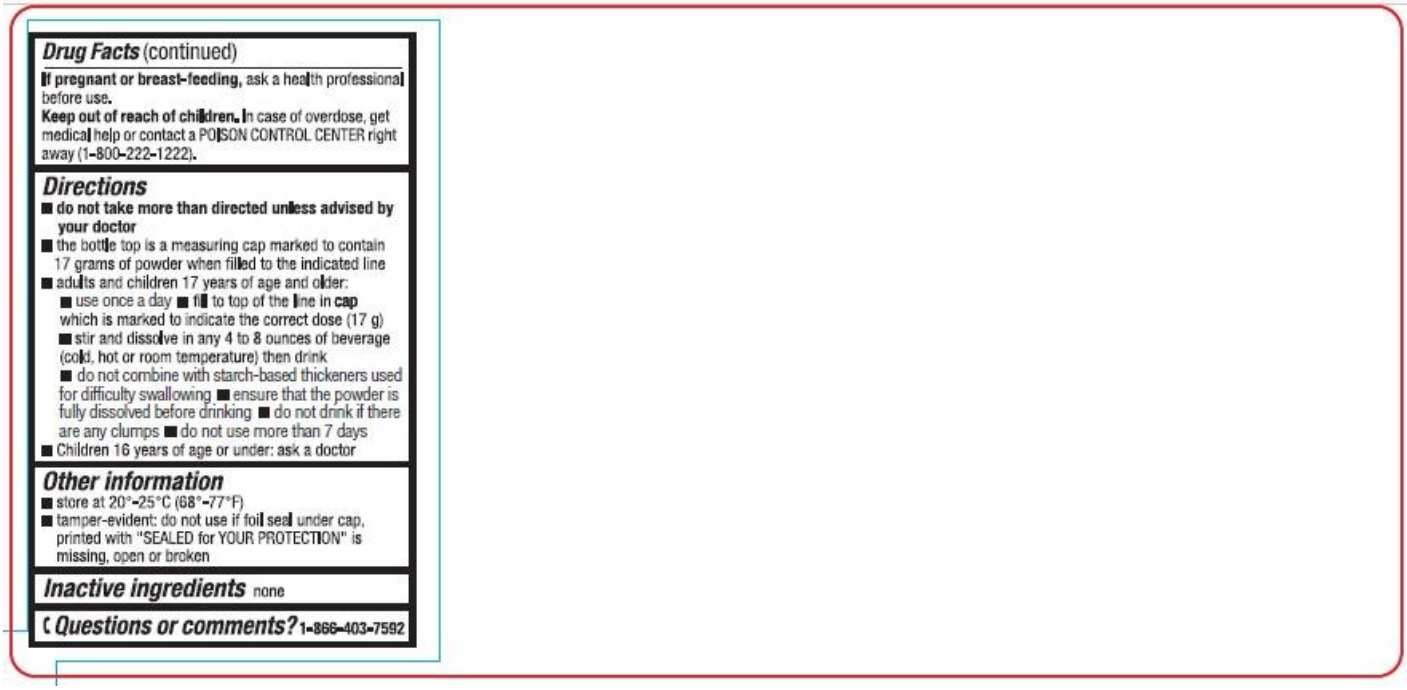
Powder for Solution, 17g/dose

Osmotic Laxative

14 ONCE-DAILY DOSES

NET WT 8.3 OZ (238 g)





POLYETHYLENE GLYCOL

polyethylene glycol powder, for suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:68001-505
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

Inactive Ingredients

Ingredient Name	Strength
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Product Characteristics

Color	white	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68001-505-55	238 g in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2021	
2	NDC:68001-505-69	510 g in 1 BOTTLE; Type 0: Not a Combination Product	06/18/2021	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091077	06/18/2021	

Labeler - BluePoint Laboratories (985523874)

Establishment

Name	Address	ID/FEI	Business Operations
Novel Laboratories Inc.		793518643	analysis(68001-505) , manufacture(68001-505) , pack(68001-505)

Revised: 9/2021 BluePoint Laboratories