

**POLYETHYLENE GLYCOL 3350- polyethylene glycol 3350 powder, for solution**  
**ATLANTIC BIOLOGICALS CORP.**

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**Polyethylene Glycol 3350, NF Powder for Oral Solution**

***Drug Facts***

**Active ingredient (in each dose)**

Polyethylene Glycol 3350, 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 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:
  - 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
  - Ensure that the powder is fully dissolved before drinking.
  - Do not drink if there are any clumps.
  - use once a day
  - use no more than 7 days
- children 16 years of age or younger: ask a doctor

## Other information

- store at 20° - 25°C (68° - 77°F)
- tamper-evident: do not use if seal under cap printed with "SEALED for YOUR PROTECTION" is missing, open or broken.

## Inactive ingredients

none

## Questions or Comments?

**call: 1-800-367-3395**

Manufactured by:  
LGM Pharma Solutions, LLC  
Irvine, CA 92614

## DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.  
MIAMI, FL 33179

## PRINCIPAL DISPLAY PANEL - 510 g Bottle Label

Polyethylene Glycol

3350 NF

Powder For Solution,  
Osmotic Laxative

- Relieves Occasional Constipation/ Irregularity
- Softens stool

**17856-0962-01**  
**POLYETHYLENE GLYCOL**  
**(3350 NF )**  
**POWDER FOR SOLUTION**  
**DELIVERS 4GM**



See package insert for indications and dosage schedule

Store at 20° - 25°C (68°-77°F) OSMOTIC  
LAXATIVE  
KEEP OUT OF THE REACH OF CHILDREN



**17856-0962-01**

**Dosage: 4 GM**

**POLYETHYLENE GLYCOL**

**Qty: 72 POUCHES**



**GTIN: 00117856096214**

**S/N: 01310801**

**Exp: 08/16/21**

**Lot: 013108**

**OTC**

Packaged by: Unit Dose Solutions  
Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp,  
Miami FL 33179

Rev. 09/19

**Call to Reorder: 800.509.7592**

**17856-0962-02**  
**POLYETHYLENE GLYCOL**  
**(3350 NF )**  
**POWDER FOR SOLUTION**  
**DELIVERS 4.25GM**



See package insert for indications and dosage schedule

Store at 20° - 25°C (68° - 77°F) OSMOTIC  
LAXATIVE  
KEEP OUT OF THE REACH OF CHILDREN



**17856-0962-02**

**Dosage: 4.25 GM**

**POLYETHYLENE GLYCOL      Qty: 72 POUCHES**



GTIN: 00117856096221

S/N: 01310901

Exp: 08/16/21

Lot: 013109

**OTC**

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Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp,  
Miami FL 33179

Rev. 09/19

**Call to Reorder: 800.509.7592**

**17856-0962-03**  
**POLYETHYLENE GLYCOL**  
**(3350 NF )**  
**POWDER FOR SOLUTION**  
**DELIVERS 8.5 GM**



See package insert for indications and dosage schedule

Store at 20°- 25°C (68°-77°F) OSMOTIC  
LAXATIVE  
KEEP OUT OF THE REACH OF CHILDREN



**17856-0962-03**

**Dosage: 8.5 GM**

**POLYETHYLENE GLYCOL**

**Qty: 50 CUPS**



**GTIN: 00117856096238**

**S/N: 01311001**

**Exp: 08/16/21**

**Lot: 013110**

**OTC**

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Morrisville, NC 27560

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**17856-0962-04**  
**POLYETHYLENE GLYCOL**  
**(3350 NF.)**  
**POWDER FOR SOLUTION**  
**DELIVERS 8.5 GM**



See package insert for indications and dosage schedule

Store at 20°- 25°C (68°-77°F ) OSMOTIC  
LAXATIVE  
KEEP OUT OF THE REACH OF CHILDREN



**17856-0962-04**

**Dosage: 8.5 GM**

**POLYETHYLENE GLYCOL Qty: 72 POUCHES**



GTIN: 00117856096245

S/N: 01311101

Exp: 08/16/21

Lot: 013111

**OTC**

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Rev.09/19

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## **POLYETHYLENE GLYCOL 3350**

polyethylene glycol 3350 powder, for solution

### **Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17856-0962(NDC:51991-962)
<b>Route of Administration</b>	ORAL		

### **Active Ingredient/Active Moiety**

<b>Ingredient Name</b>	<b>Basis of Strength</b>	<b>Strength</b>
<b>POLYETHYLENE GLYCOL 3350</b> (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:17856-0962-1	72 in 1 BOX, UNIT-DOSE	02/17/2021	
1		4 g in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:17856-0962-2	72 in 1 BOX, UNIT-DOSE	02/17/2021	
2		4.25 g in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:17856-0962-3	50 in 1 BOX, UNIT-DOSE	02/17/2021	
3		8.50 g in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
4	NDC:17856-0962-4	72 in 1 BOX, UNIT-DOSE	02/17/2021	
4		8.50 g in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:17856-0962-5	50 in 1 BOX, UNIT-DOSE	06/08/2021	
5		4.25 g in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		

**Marketing Information**

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090812	03/27/2019	

**Labeler** - ATLANTIC BIOLOGICALS CORP. (047437707)**Establishment**

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	relabel(17856-0962) , repack(17856-0962)

Revised: 6/2021

ATLANTIC BIOLOGICALS CORP.