

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

Active ingredient (in each dose)

Polyethylene Glycol 3350, 17 grams (cap filled to the indicated "17 GRAMS" line)

Purpose

Laxative

Uses

- 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 cap is a measuring cup marked to contain 17 grams of powder when filled to the indicated "17 GRAMS" line
- adults and children 17 years of age and older:
- fill to indicated "17 GRAMS" line in cap 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
- 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 foil seal under cap printed with “SEALED for YOUR PROTECTION” is missing, open or broken.

Inactive ingredients

none

DISTRIBUTED BY:

ATLANTIC BIOLOGICALS CORP.

20101 N.E 16 TH PLACE

MIAMI, FL 33179

For serious adverse events call:

1-888-710-0006

Package label

NDC 17856-0489-01
Polyethylene Glycol 3350

Powder for Oral Solution

Prescription Laxative

Sugar Free

UNIT DOSE 17 Grams Cup

Compare to the active ingredient in MiraLAX®*

PACKAGING INFORMATION:

Dosage per Cup: 17 Grams

Cups per Case: 50

See Package Insert for Drug Facts

Other Information:

Store at 20°- 25°C (68°- 77°F)

**KEEP POLYETHYLENE GLYCOL AND ALL MEDICINES
OUT OF THE REACH OF CHILDREN**

MFG by: Gericare Pharmaceuticals
1650 63rd Street, Brooklyn, NY 11204
Repackaged by: Unit Dose Solutions, Inc., Morrisville, NC 27560
Distributed by: Atlantic Biologicals Corp.
20101 N.E. 16th Place
Miami, FL 33179

*Retain box label and package insert for drug information.

Questions or Comments:

Call 1-800-509-7592

Lot No: XXXXXX
MFG Lot No: XXXXXXX
Exp Date: XX/XX/XXXX



17856048901

NDC 17856-0489-03
Polyethylene Glycol 3350

Powder for Oral Solution

Prescription Laxative

Sugar Free

UNIT DOSE 4 Grams Bag

Compare to the active ingredient in MiraLAX®*

PACKAGING INFORMATION:

Dosage per Bag: 4 Grams

Bags per Case: 72

See Package Insert for Drug Facts

Other Information:

Store at 20°- 28°C (68°- 77°F)

**KEEP POLYETHYLENE GLYCOL AND ALL MEDICINES
OUT OF THE REACH OF CHILDREN**

MFG by: Gericare Pharmaceuticals
1650 63rd Street, Brooklyn, NY 11204
Repackaged by: Unit Dose Solutions, Inc., Morrisville, NC 27560
Distributed by: Atlantic Biologicals Corp.
20101 N.E. 16th Place
Miami, FL 33179

*Retain box label and package insert for drug information.

Questions or Comments:

Call 1-800-509-7592

Lot No: XXXXXX
MFG Lot No: XXXXXXX
Exp Date: XX/XX/XXXX



17856048903

NDC 17856-0489-05
Polyethylene Glycol 3350

Powder for Oral Solution

Prescription Laxative

Sugar Free

UNIT DOSE 8.5 Grams Cup

Compare to the active ingredient in MiraLAX®*

PACKAGING INFORMATION:

Dosage per Cup: 8.5 Grams
Cups per Case: 50

See Package Insert for Drug Facts

Other Information:

Store at 20°- 25°C (68°- 77°F)

**KEEP POLYETHYLENE GLYCOL AND ALL MEDICINES
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MFG by: Gericare Pharmaceuticals
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Questions or Comments:

Call 1-800-509-7592

Lot No: XXXXXX
MFG Lot No: XXXXXX
Exp Date: XX/XX/XXXX



17856048905

POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-0489(NDC:57896-489)
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:17856-0489-1	50 in 1 BOX, UNIT-DOSE	08/07/2018	
1		17 g in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
2	NDC:17856-0489-2	72 in 1 BOX, UNIT-DOSE	08/07/2018	
2		17 g in 1 BAG; Type 0: Not a Combination Product		
3	NDC:17856-0489-3	72 in 1 BOX, UNIT-DOSE	08/07/2018	
3		4 g in 1 BAG; Type 0: Not a Combination Product		
4	NDC:17856-0489-4	72 in 1 BOX, UNIT-DOSE	08/07/2018	
4		4.25 g in 1 BAG; Type 0: Not a Combination Product		
5	NDC:17856-0489-5	50 in 1 BOX, UNIT-DOSE	08/07/2018	
5		8.5 g in 1 CUP, UNIT-DOSE; Type 0: Not a Combination Product		
6	NDC:17856-0489-6	72 in 1 BOX, UNIT-DOSE	08/07/2018	
6		8.5 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	08/07/2018	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Establishment			
Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP		047437707	relabel(17856-0489) , repack(17856-0489)

Revised: 8/2018

ATLANTIC BIOLOGICALS CORP.