

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

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***Drug Facts***

**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:
- 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
- use once a day
- use no 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 printed foil seal under cap is missing, open or broken

**Inactive Ingredient**

none

***Questions or comments?***

**1-866-403-7592**

**GAVILAX (POLYETHYLENE GLYCOL-3350) POWDER, FOR SOLUTION**

**17856-0312-05**

**GaviLAX (Polyethylene Glycol  
3350) Powder for Oral  
Solution Osmotic Laxative**



See package insert for indications and dosage schedule



17856031205

**OSMOTIC LAXATIVE** Compare to MiraLAX®\*  
Store at 20°-25°C (68°-77°F)  
**KEEP OUT OF THE REACH OF CHILDREN**

**17856-0312-05**

**Dosage: 8.5gm**

**GaviLAX**

**Qty: 50 CUPS**



**GTIN: 00117856031253**

**S/N: 01059801**

**Exp: 12/08/20**

**Lot: 010598**

**OTC**

Packaged by: Unit Dose Solutions  
Morriville, NC 27560

Distributed by: Atlantic Biologicals Corp.  
Miami, FL 33179

Rev. 09/19

**Call to Reorder: 800.509.7592**

**17856-0312-02**  
**GaviLAX (Polyethylene Glycol 3350) Powder for Oral Solution**



See package insert for indications and dosage schedule

Store at 20°-25°C (68°-77°F)  
Osmotic Laxative. Compare to MiraLAX®\*  
**KEEP OUT OF THE REACH OF CHILDREN**



**17856-0312-02**

**Dosage: 8.5 gm Pouch**

**GaviLAX**

**Qty: 72 POUCHES**

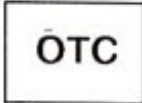


**GTIN: 00117856031222**

**S/N: 01059901**

**Exp: 12/08/20**

**Lot: 010599**



Packaged by: Unit Dose Solutions  
Morrieville, NC 27560

Distributed by: AtlanticBiologicals Corp,  
Miami FL 33179

Rev 09/19

**Call to Reorder: 800.509.7592**

**17856-0312-06**  
**GaviLAX (Polyethylene Glycol 3350) Powder for Oral Solution Osmotic Laxative**



See package insert for indications and dosage schedule



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

**17856-0312-06 Dosage: 4.25GM Pouch**

**GaviLAX Qty: 72 POUCHES**



GTIN: 00117856031260  
 S/N: 00955401  
 Exp: 08/20/20  
 Lot: 009554

**OTC**

Packaged by: Unit Dose Solutions  
 Morrisville, NC 27560

Distributed by: AtlanticBiologicals Corp.  
 Miami FL 33179

Rev. 09/19

**Call to Reorder: 800.509.7592**

**GAVILAX**

polyethylene glycol 3350 powder, for solution

**Product Information**

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:17856-0312(NDC:43386-312)
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	17 g in 17 g

**Inactive Ingredients**

Ingredient Name	Strength
<b>SODIUM HYDROXIDE</b> (UNII: 55X04QC32I)	

**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:17856-0312-1	17 g in 1 BAG; Type 0: Not a Combination Product	01/26/2021	
2	NDC:17856-0312-2	8.5 g in 1 BAG; Type 0: Not a Combination Product	01/26/2021	
3	NDC:17856-0312-3	17 g in 1 CUP; Type 0: Not a Combination Product	01/26/2021	
4	NDC:17856-0312-4	4 g in 1 BAG; Type 0: Not a Combination Product	01/26/2021	
5	NDC:17856-0312-5	50 in 1 CASE	01/26/2021	
5		8.5 g in 1 CUP; Type 0: Not a Combination Product		
6	NDC:17856-0312-6	72 in 1 CASE	01/26/2021	
6		4.5 g in 1 POUCH; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091077	10/09/2009	

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

**Registrant** - ATLANTIC BIOLOGICALS CORP. (047437707)

### Establishment

Name	Address	ID/FEI	Business Operations
ATLANTIC BIOLOGICALS CORP.		047437707	RELABEL(17856-0312) , REPACK(17856-0312)

Revised: 1/2021

ATLANTIC BIOLOGICALS CORP.