

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

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

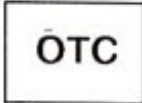


GTIN: 00117856031222

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: AtlanticBiologics Corp.
 Miami Fl 33179

Rev. 09/19

Call to Reorder: 800.509.7592

GAVILAX
 polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:17856-0312(NDC:43386-312)
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: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:17856-0312-7	50 in 1 BOX, UNIT-DOSE	10/10/2023	
5	NDC:17856-0312-8	4.25 g in 1 BAG; Type 0: Not a Combination Product		
6	NDC:17856-0312-5	50 in 1 CASE	01/26/2021	
6		8.5 g in 1 CUP; Type 0: Not a Combination Product		
7	NDC:17856-0312-6	72 in 1 CASE	01/26/2021	
7		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)

Establishment

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

Revised: 10/2023

ATLANTIC BIOLOGICALS CORP.