

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

Gavilax Powder Solution
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

17856-0312-02
GAVILAX POWDER
(Polyethylene Glycol 3350)
ORAL SOLUTION
DELIVERS 8.5 GRAMS



See package insert for indications and dosage schedule

Osmatic Laxative for those 17 yrs of age and older. Stir and dissolve completely in beverage, then drink. DO NOT drink if there are clumps. Store at Room Temperature 20°-25°C (68°-77°F). Compare to MiraLAX®
****Keep this and all Medications out of the reach of children****



217856031202

17856-0312-02 Dosage 8.5 gm POUCH

GAVILAX POWDER
(Polyethylene Glycol 3350) Qty: **72 POUCHES**



GTIN: 00317856031226
S/N: XXXXXXXXXXXX
Exp: 11/08/24
Lot: XXXXXXXXXXXX



Packaged by:

Distributed by: Atlantic Biologicals Corp.
Miami, FL 33179

Rev.08/21

Call to Reorder:

17856-0312-04
GAVILAX POWDER
(Polyethylene Glycol 3350)
ORAL SOLUTION
DELIVERS 4 GRAMS



See package insert for indications and dosage schedule

Osmatic Laxative for those 17 yrs of age and older. Stir and dissolve completely in beverage, then drink. DO NOT drink if there are clumps. Store at Room Temperature 20°-25°C (68°-77°F). Compare to MiraLAX®
****Keep this and all Medications out of the reach of children****



217856031204

17856-0312-04 Dosage 4gm Pouch

GAVILAX POWDER
(Polyethylene Glycol 3350) Qty: **72 POUCHES**



GTIN: 00317856031240
S/N: XXXXXXXXXXXX
Exp: 11/11/24
Lot: XXXXXXXXXXXX



Packaged by:

Distributed by: Atlantic Biologicals Corp.
Miami, FL 33179

Rev.08/21

Call to Reorder:

17856-0312-05
GaviLAX
(Polyethylene Glycol 3350)
ORAL SOLUTION
DELIVERS 8.5 GRAMS



See package insert for indications and dosage schedule

Osmatic Laxative for those 17 yrs of age and older. Stir and dissolve completely in beverage, then drink. DO NOT drink if there are clumps. Store at Room Temperature 20°-25°C (68°-77°F). Compare to MiraLAX®*
Keep this and all Medications out of the reach of children



17856031205

17856-0312-05 Dosage 8.5 GRAMS

GaviLAX (Polyethylene Glycol 3350)

Qty: 50 CUPS



GTIN: 00317856031257

S/N: XXXXXXXXXXXX

Exp: 06/03/25

Lot: XXXXXXXXXXXX



Packaged by: Unit Dose Solutions
Morrisville, NC 27560

Distributed by: Atlantic Biologicals Corp.
Miami, FL 33179

Rev.08/21

Call to Reorder:

17856-0312-08
GAVILAX POWDER
(Polyethylene Glycol 3350)
ORAL SOLUTION
DELIVERS 4.25 GRAMS



See package insert for indications and dosage schedule

Osmatic Laxative for those 17 yrs of age and older. Stir and dissolve completely in beverage, then drink. DO NOT drink if there are clumps. Store at Room Temperature 20°-25°C (68°-77°F). Compare to MiraLAX®
****Keep this and all Medications out of the reach of children****



17856031208

17856-0312-08 Dosage 4.25GM Pouch

GAVILAX POWDER
(Polyethylene Glycol 3350) Qty: **72 POUCHES**



GTIN: 00317856031288
S/N: XXXXXXXXXXXX
Exp: 07/22/25
Lot: XXXXXXXXXXXX



Packaged by:

Distributed by: Atlantic Biologicals Corp.
Miami, FL 33179

Rev.08/21

Call to Reorder:

17856-0312-09
GAVILAX POWDER
(Polyethylene Glycol 3350)
ORAL SOLUTION
DELIVERS 4.25 GRAMS



17856031209

See package insert for indications and dosage schedule

Osmatic Laxative for those 17 yrs of age and older. Stir and dissolve completely in beverage, then drink. DO NOT drink if there are clumps. Store at Room Temperature 20°-25°C (68°-77°F). Compare to MiraLAX®
****Keep this and all Medications out of the reach of children****

17856-0312-09 Dosage 4.25GM CUP

GAVILAX POWDER
(Polyethylene Glycol 3350) Qty: **72 CUPS**



GTIN: 00317856031295

S/N: XXXXXXXXXXXX

Exp: 07/22/25

Lot: XXXXXXXXXXXX



Packaged by:

Distributed by: Atlantic Biologicals Corp.
Miami, FL 33179

Rev.08/21

Call to Reorder:

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		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		
8	NDC:17856-0312-8	72 in 1 BOX, UNIT-DOSE	07/22/2025	
8		4.25 g in 1 BAG; Type 0: Not a Combination Product		
9	NDC:17856-0312-9	50 in 1 BOX, UNIT-DOSE	07/22/2025	
9		4.25 g in 1 CUP; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA091077	01/26/2021	

Labeler - ATLANTIC BIOLOGICALS CORP. (047437707)

Revised: 7/2025

ATLANTIC BIOLOGICALS CORP.