

**GAVILAX- polyethylene glycol 3350 powder, for solution  
Proficient Rx LP**

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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**

## **PACKAGE LABEL.PRINCIPAL DISPLAY PANEL**

**NDC 63187-368-23**

Original Prescription Strength

**GaviLax**

Polyethylene Glycol 3350

Powder for Solution, Osmotic Laxative

**14 ONCE-DAILY DOSES**

**NET WT 8.3 OZ (238 g)**

**Relabeled by:**

**Proficient Rx LP**

**Thousand Oaks, CA 91320**



Scan Here



NDC 63187-368-23

Relabeled By: Proficient Rx LP  
Thousand Oaks, CA 91320

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6318736823  
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# Polyethylene Glycol 3350

8.3 OZ (238 g) Powder

Each dose contains: Polyethylene Glycol 3350,  
17 g (cap filled to line) Osmotic Laxative

See Bottle

Product ID: RP036823

Mfr. For: Lupin Pharmaceuticals, Inc. Baltimore, MD 21202

Store at 20°-25°C (68°-77°F)

Keep medication out of the reach of children

Polyethylene Glycol 3350  
8.3 OZ (238 g) Powder  
Lot #:00000 SN# MASTER  
NDC 63187-368-23 Exp:00/00/00

Polyethylene Glycol 3350  
8.3 OZ (238 g) Powder  
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Polyethylene Glycol 3350  
8.3 OZ (238 g) Powder  
Lot #:00000 SN# MASTER  
NDC 63187-368-23 Exp:00/00/00



GTIN: 00363187368234  
SN# MASTER  
Exp. 00/00/00  
Lot #:00000

## GAVILAX

polyethylene glycol 3350 powder, for solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63187-368(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

<b>1</b>	NDC:63187-368-23	238 g in 1 BOTTLE; Type 0: Not a Combination Product	09/01/2016	
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## Marketing Information

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

**Labeler** - Proficient Rx LP (079196022)

## Establishment

Name	Address	ID/FEI	Business Operations
Proficient Rx LP		079196022	REPACK(63187-368) , RELABEL(63187-368)

Revised: 6/2022

Proficient Rx LP