

GAVILAX- polyethylene glycol 3350 powder, for solution
Preferred Pharmaceuticals, Inc.

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

Relabeled by Preferred Pharmaceuticals, Inc.

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 68788-7508-02

Original Prescription Strength

GaviLax

Polyethylene Glycol 3350

Powder for Solution, Osmotic Laxative

14 ONCE-DAILY DOSES

NET WT 8.3 OZ (238 g)

GaviLAX

Generic for Miralax

Each gm contains Polyethylene Glycol 3350

Pkg Size: Exp Date:

Lot#:

Batch#:

Ins:

Mfg: Lupin Pharmaceuticals, Inc.

Prod#:

Warning

Store at 20°-25°C (68°-77°F). See bottle for directions. In case of overdose, get medical help or contact a Poison Control Center right away. If pregnant or breast-feeding, ask a health professional before use. Do not use if original foil seal under cap is missing, open or broken. Do not use if you are allergic to polyethylene glycol. Keep this and all medication out of the reach of children.



Asheville, Ca 92007



Directions English

Use as directed on package.
Use as directed by your doctor



Instrucciones Espanol:

Utilice como dirigido en el paquete.
Uso según lo dirigido por su doctor

GaviLAX

Qty: Ins:

Lot#: Bat#:

Prod# (NDC):

GaviLAX

Qty: Ins:

Lot#: Bat#:

Prod# (NDC):

GaviLAX

Qty: Ins:

Insurance NDC:

Lot#: Bat#:

GaviLAX

Qty: Ins:

Lot#: Bat#:

Prod# (NDC):

Log

Chart

Billing

Patient

GAVILAX

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:68788-7508(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:68788-7508-2	238 g in 1 BOTTLE; Type 0: Not a Combination Product	10/28/2019	

Marketing Information

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

Labeler - Preferred Pharmaceuticals, Inc. (791119022)

Registrant - Preferred Pharmaceuticals, Inc. (791119022)

Establishment

Name	Address	ID/FEI	Business Operations
Preferred Pharmaceuticals, Inc.		791119022	RELABEL(68788-7508)

Revised: 5/2021

Preferred Pharmaceuticals, Inc.