

GAVILAX- polyethylene glycol 3350 powder, for solution
Lupin 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
- ensure that the powder is fully dissolved before drinking
- do not drink if there are any lumps
- 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, printed with "SEALED for YOUR PROTECTION" is missing, open or broken

Inactive Ingredient

none

Questions or comments?

1-866-403-7592

PACKAGE LABEL PRINCIPAL DISPLAY PANEL

NDC 43386-312-08

Original Prescription Strength

GaviLax

Polyethylene Glycol 3350

Powder for Solution, Osmotic Laxative

14 ONCE-DAILY DOSES

NET WT 8.3 OZ (238 g)

Compare to MiraLAX®

NDC 43386-312-08

Original Prescription Strength

GaviLAX

Polyethylene Glycol 3350 Powder for Oral Solution, Osmotic Laxative

- Relieves Occasional Constipation (irregularity)
- Softens Stool

LUPIN 14 ONCE-DAILY DOSES NET WT 8.3 OZ (238 g)

Unvarnished area

3/8" White Space Area

*MiraLAX® is a registered trademark of Bayer Healthcare LLC

Manufactured for:
Lupin Pharmaceuticals, Inc.
Baltimore, MD 21202

LA312080207 SAP code: 263485 02/2020

3 43386-312-08 5

3/8" White Space Area

Drug Facts

Active ingredient (in each dose) Purpose
Polyethylene Glycol 3350,
17 g (cap filled to line).....Osmotic Laxative

Use
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■ nausea, vomiting, or abdominal pain
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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

Polyethylene Glycol 3350 increases frequency of bowel movements and softens the stool.

Dissolves in any beverage
Sugar Free

Peel Here →

Drug Facts (continued)

If pregnant or breast-feeding, ask a health professional before use.

Keep out of 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 the 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

■ ensure that the powder is fully dissolved before drinking

■ do not drink if there are any lumps

■ 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 foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken

Inactive ingredients none

Questions or comments? 1-866-403-7592

NDC 43386-312-14

Original Prescription Strength

GaviLax

Polyethylene Glycol 3350

Powder for Solution, Osmotic Laxative

30 ONCE-DAILY DOSES

NET WT 17.9 OZ (510 g)

<p>Compare to MiraLAX[®]</p> <p>NDC 43386-312-14</p> <p>Original Prescription Strength</p> <p>GaviLAX</p> <p><i>Polyethylene Glycol 3350 Powder for Oral Solution, Osmotic Laxative</i></p> <ul style="list-style-type: none"> • Relieves Occasional Constipation (irregularity) • Softens Stool <p>LUPIN 30 ONCE-DAILY DOSES NET WT 17.9 OZ (510 g)</p>	<p>.5625" White Space Area</p>	<p>Unvarnished area</p> <p>*MiraLAX[®] is a registered trademark of Bayer Healthcare LLC</p> <p>Manufactured for: Lupin Pharmaceuticals, Inc. Baltimore, MD 21202</p> <p>LA3121400207 SAP code: 263486 02/2020</p>  <p>N 3 43386-312-14 6</p>	<p>.5625" White Space Area</p>	<p>Drug Facts</p> <p>Active ingredient (in each dose).....Purpose Polyethylene Glycol 3350, 17 g (cap filled to line).....Osmotic Laxative</p> <p>Use</p> <ul style="list-style-type: none"> • relieves occasional constipation (irregularity) • generally produces a bowel movement in 1 to 3 days <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to polyethylene glycol</p> <p>Do not use if you have kidney disease, except under the advice and supervision of a doctor</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> • nausea, vomiting, or abdominal pain • a sudden change in bowel habits that lasts over 2 weeks • irritable bowel syndrome <p>Ask a doctor or pharmacist before use if you are taking a prescription drug</p> <p>When using this product you may have loose, watery, more frequent stools</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> • 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 	<p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use. Keep out of reach of children. In case of overdose, get medical help or contact a POISON CONTROL CENTER right away. (1-800-222-1222)</p> <p>Directions</p> <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • fill to top of the 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 • ensure that the powder is fully dissolved before drinking • do not drink if there are any lumps • use once a day • use no more than 7 days • Children 16 years of age or under: ask a doctor <p>Other information</p> <ul style="list-style-type: none"> • store at 20°-25°C (68°-77°F) • tamper-evident: do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken <p>Inactive ingredients none</p> <p>Questions or comments? 1-866-403-7592</p> <p>Polyethylene Glycol 3350 increases frequency of bowel movements and softens the stool</p> <p><i>Dissolves in Any Beverage Sugar free</i></p>
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GAVILAX

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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 HYDRO XIDE (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:43386-312-07	119 g in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2009	
2	NDC:43386-312-85	850 g in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2009	
3	NDC:43386-312-14	510 g in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2009	
4	NDC:43386-312-08	238 g in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2009	

Marketing Information

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

Labeler - Lupin Pharmaceuticals, Inc. (089153071)

Registrant - Novel Laboratories, Inc. (793518643)

Establishment

Name	Address	ID/FEI	Business Operations
Novel Laboratories, Inc.		793518643	analysis(43386-312) , manufacture(43386-312) , pack(43386-312)