

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

Drug Facts

Active Ingredient

Polyethylene Glycol 3350, 17 g (cap filled to line).....Osmotic Laxative

Purpose

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:
 - use once a day
 - 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
 - do not combine with starch-based thickeners used for difficulty swallowing
 - ensure that the powder is fully dissolved before drinking
 - do not drink if there are any clumps
 - do not use 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

- Dissolves in any beverages
- Sugar Free

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 43386-312-08

Original Prescription Strength

GaviLax

Polyethylene Glycol 3350

Powder for Oral 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)

3/8" White Space Area

Unvarnished area

*MiraLAX[®] is a registered trademark of Bayer Healthcare LLC

Manufactured for:
Lupin Pharmaceuticals, Inc.
Naples, FL 34108

SAP Code: 276637; Rev. 10/2024



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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Warnings

Allergy alert: Do not use if you are allergic to polyethylene glycol

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- 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

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
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 - use once a day
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 - ensure that the powder is fully dissolved before drinking
 - do not drink if there are any clumps
 - do not use 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 43386-312-85

Original Prescription Strength

GaviLax

Polyethylene Glycol 3350

Powder for Oral Solution, Osmotic Laxative

50 ONCE-DAILY DOSES

NET WT 29.9 OZ (850 g)

Compare to MiraLAX®

NDC 43386-312-85

Original Prescription Strength

GaviLAX

Polyethylene Glycol 3350 Powder for Oral Solution, Osmotic Laxative

- Relieves Occasional Constipation (irregularity)
- Softens Stool

LUPIN® 50 ONCE-DAILY DOSES
NET WT 29.9 OZ (850 g)

.6 White Space Area

Unvarnished Area

*MiraLAX® is a registered trademark of Bayer Healthcare LLC

Manufactured for:
Lupin Pharmaceuticals, Inc.
Naples, FL 34108

SAP Code: 276539
Rev. 10/2024

3 43386-312-85 6

Drug Facts	
Active ingredient (in each dose) 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 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: ■ use once a day ■ 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 ■ do not combine with starch-based thickeners used for difficulty swallowing ■ ensure that the powder is fully dissolved before drinking ■ do not drink if there are any clumps ■ do not use 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? 1-866-403-7982	
Dissolves in any beverage Sugar Free	
Polyethylene Glycol 3350 increases frequency of bowel movements and softens the stool.	

NDC 43386-312-07

Original Prescription Strength

GaviLax

Polyethylene Glycol 3350

Powder for Oral Solution, Osmotic Laxative

7 ONCE-DAILY DOSES

NET WT 4.1 OZ (119 g)

Compare to MiraLAX®

NDC 43386-312-07

Original Prescription Strength

GaviLAX

Polyethylene Glycol 3350 Powder for Oral Solution, Osmotic Laxative

- Relieves Occasional Constipation (irregularity)
- Softens Stool

LUPIN® 7 ONCE-DAILY DOSES
NET WT 4.1 OZ (119 g)

White Space Area .453"

UNVARNISHED AREA

*MiraLAX® is a registered trademark of Bayer Healthcare LLC

Manufactured for:
Lupin Pharmaceuticals, Inc.
Naples, FL 34108

SAP Code: 276536; Rev. 10/2024

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Drug Facts		Drug Facts (continued)
Active ingredient (in each dose) Polyethylene Glycol 3350, 17 g (cap filled to line)	Purpose Osmotic Laxative	Ask a doctor or pharmacist before use if you are taking a prescription drug
Use ■ relieves occasional constipation (irregularity) ■ generally produces a bowel movement in 1 to 3 days		When using this product you may have loose, watery, more frequent stools
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		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.		Peel Here

<p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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"> use once a day 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 	<p>Drug Facts (continued)</p> <ul style="list-style-type: none"> or room temperature) then drink do not combine with starch-based thickeners used for difficulty swallowing ensure that the powder is fully dissolved before drinking do not drink if there are any clumps do not use 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>→ Dissolves in any beverage → Sugar Free</p>
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NDC 43386-312-14
Original Prescription Strength
GaviLax
Polyethylene Glycol 3350
Powder for Oral Solution, Osmotic Laxative
30 ONCE-DAILY DOSES
NET WT 17.9 OZ (510 g)

<p>Compare to MiraLAXSM</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>.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>Polyethylene Glycol 3350 increases frequency of bowel movements and softens the stool</p>	<p>Drug Facts (continued)</p> <p>If pregnant or breast-feeding, ask a health professional before use.</p> <p>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"> use once daily 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 do not combine with starch-based thickeners used for difficulty swallowing ensure that the powder is fully dissolved before drinking do not drink if there are any clumps do not use 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>Dissolves in Any Beverage Sugar free</p>
				<p>*MiraLAX[®] is a registered trademark of Bayer Healthcare LLC</p> <p>Manufactured for: Lupin Pharmaceuticals, Inc. Naples, FL 34108</p> <p>SAP Code: 276538 Rev. 10/2024</p> <p>N 3 43386-312-14 6</p>	

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 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:43386-312-14	510 g in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2009	
2	NDC:43386-312-08	238 g in 1 BOTTLE; Type 0: Not a Combination Product	10/09/2009	
3	NDC:43386-312-07	119 g in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2040	
4	NDC:43386-312-85	850 g in 1 BOTTLE; Type 0: Not a Combination Product	01/31/2040	

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)