POLYETHYLENE GLYCOL 3350- polyethylene glycol 3350 powder, for solution
Breeckenridge Pharmaceutical, Inc.

Polyethylene Glycol 3350, NF Powder for Oral Solution

Drug Facts

Active ingredient (in each dose)

Polyethylene Glycol 3350, 17 g (cup filled to the indicated "17 GRAMS" 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.

Directions

- **do not take more than directed unless advised by your doctor**
- this product is supplied with a dosing cup 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 the indicated "17 GRAMS" line on cup 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?

***call:* 1-800-367-3395**

Manufactured by:
LGM Pharma Solutions, LLC
Irvine, CA 92614

Distributed by:
Breckenridge Pharmaceutical, Inc.
Berlin, CT 06037

PRINCIPAL DISPLAY PANEL - 238 g Bottle Label

NDC 51991-961-58

Polyethylene Glycol
3350, NF

Powder for Solution,
Osmotic Laxative

- Relieves Occasional Constipation / Irregularity
- Softens Stool

- Unflavored Powder
- Sugar Free

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

breckenridge
A Towa
Company

NDC 51991-961-58

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Powder for Solution, Osmotic Laxative

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- Sugar Free

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

breckenridge | A Towa Company

Dissolves in Any Beverage

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

Manufactured by:
LGM Pharma Solutions, LLC
Irvine, CA 92614

Distributed by:
Breckenridge Pharmaceutical, Inc.
Berlin, CT 06037

Rev 01/2022 7116-0238-35-EC

3 51991 96158 1

Tamper-evident: do not use if foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken.

Lot No.:
Exp. Date:

Lift Here

Drug Facts

Active ingredient (in each dose) ***Purpose***

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Drug Facts (continued)

Inactive ingredients none

Questions or Comments? call: 1-800-367-3395

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Irvine, CA 92614

Distributed by:
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Berlin, CT 06037

Rev 01/2022 7116-0238-35-EC

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Drug Facts

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Drug Facts (continued)

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- you get diarrhea
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Drug Facts (continued)

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PRINCIPAL DISPLAY PANEL - 510 g Bottle Label

NDC 51991-962-57

Polyethylene Glycol
3350, NF

Powder for Solution,
Osmotic Laxative

- Relieves Occasional Constipation/ Irregularity
- Softens Stool
- Unflavored Powder
- Sugar Free

NET WT 17.9 OZ (510 g)
30 ONCE - DAILY DOSES

breckenridge
A Towa
Company

NDC 51991-962-57

Polyethylene Glycol 3350, NF

Powder for Solution, Osmotic Laxative

- Relieves Occasional Constipation/ Irregularity
- Softens Stool
- Unflavored Powder
- Sugar Free

NET WT 17.9 OZ (510 g)
30 ONCE - DAILY DOSES

breckenridge | A Towa Company

Dissolves in Any Beverage

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

Manufactured by:
LGM Pharma Solutions, LLC
Irvine, CA 92614

Distributed by:
Breckenridge Pharmaceutical, Inc.
Berlin, CT 06037

3 51991 96257 1

Lot No.:
Exp. Date:

Drug Facts

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Drug Facts (continued)

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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?

1-800-367-3395

7116-0510-35-BL
Rev 01/2022

POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51991-961
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

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51991-961-58	238 g in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	09/30/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090812	03/27/2019	09/30/2024

POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:51991-962
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

Product Characteristics			
Color	WHITE	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51991-962-57	510 g in 1 BOTTLE; Type 0: Not a Combination Product	03/27/2019	07/31/2024

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090812	03/27/2019	09/30/2024

Labeler - Breeckenridge Pharmaceutical, Inc. (150554335)

Establishment

Name	Address	ID/FEI	Business Operations
LGM Pharma Solutions, LLC		117549200	MANUFACTURE(51991-961, 51991-962)

Revised: 10/2022 Breeckenridge Pharmaceutical, Inc.