

**POLYETHYLENE GLYCOL 3350- polyethylene glycol 3350 powder, for solution
GLENMARK THERAPEUTICS INC., USA**

Polyethelene Glycol 3350, Powder for Solution

Polyethylene Glycol 3350, Powder for Solution

Drug Facts

Active ingredient (in each dose) (Can only)

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

Purpose

Osmotic Laxative

Active ingredient (in each dose) (Packet Only)

Polyethylene Glycol 3350, 17 g

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.

Directions (Can Only)

- **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 (white section in cap)
- adults and children 17 years of age and older:
 - o use once a day
 - o fill to top of white section in cap which is marked to indicate the correct dose (17 g)
 - o stir and dissolve in any 4 to 8 ounces of beverage (cold, hot or room temperature) then drink
 - o do not combine with starch-based thickeners used for difficulty swallowing
 - o ensure that the powder is fully dissolved before drinking
 - o do not drink if there are any clumps
 - o do not use more than 7 days
- children 16 years of age or under: ask a doctor

Directions (Packet Only)

- **do not take more than directed unless advised by your doctor**
- adults and children 17 years of age and older:
 - o use once a day
 - o stir and dissolve one packet of powder (17 g) in any 4 to 8 ounces of beverage (cold, hot or room temperature) then drink
 - o do not combine with starch-based thickeners used for difficulty swallowing
 - o ensure that the powder is fully dissolved before drinking
 - o do not drink if there are any clumps
 - o 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 weekdays 9 AM to 5 PM at 1 (888) 721-7115

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

Distributed by

Glenmark Therapeutics Inc., USA

Mahwah, NJ 07430

PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

NDC 72657-196-16 Polyethylene Glycol 3350

Powder for Solution

Osmotic Laxative

- **Relieves Occasional Constipation (Irregularity)**
- **Softens Stool**
- **TAMPER-EVIDENT:** do not use if printed foil seal under cap is missing, open or broken ***Unflavored***
- ***Sugar Free***
- ***Dissolves in Any Beverage***

45 ONCE-DAILY DOSES

NET WT 26.9 OZ (765 g) EACH

45s Label front

NDC 72657-196-16

ORIGINAL PRESCRIPTION STRENGTH

OSMOTIC LAXATIVE

†Compare to the active ingredient of **MiraLAX®**

POLYETHYLENE GLYCOL 3350

POWDER FOR SOLUTION

Relieves occasional constipation (irregularity)
Softens stool

UNFLAVORED

SUGAR FREE

DISSOLVES IN ANY BEVERAGE



45 ONCE-DAILY DOSES

NET WT 26.9 OZ (765 g)

LCG-001-08-01

TAMPER-EVIDENT: do not use if printed foil seal under cap is missing, open or broken

45s Label back

TITLE FRONT : PAGE 01

Drug Facts	
<i>Active ingredient (in each dose)</i>	<i>Purpose</i>
Polyethylene Glycol 3350, 17 g (cap filled to line)	Osmotic Laxative
Uses	
<ul style="list-style-type: none"> 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	
<small>†This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of MiraLAX® Powder for Solution, Osmotic Laxative, and owner of the registered trademark MiraLAX®. [Bayer HealthCare LLC does not make or license Glenmark's product.]</small>	
Distributed by: Glenmark Therapeutics Inc., USA Mahwah, NJ 07430 Revised: 08/2024 LCG-001-08-01	 LOT: EXP: <div style="border: 1px dashed red; padding: 5px; margin-top: 10px; text-align: center;"> NO VARNISH ZONE [35 x 25 mm] </div>

PEEL HERE

TITLE BACK : PAGE 02

Drug Facts (continued)

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

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- 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 breastfeeding, 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**
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BASE LABEL - PAGE 03

Drug Facts (continued)

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Inactive Ingredients none

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POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:72657-196
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 (Colorless upon dissolution)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:72657-196-16	765 g in 1 CAN; Type 0: Not a Combination Product	09/19/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203928	09/19/2024	

Labeler - GLENMARK THERAPEUTICS INC., USA (969085666)

Establishment

Name	Address	ID/FEI	Business Operations
Strides Pharma Science Limited		918513263	ANALYSIS(72657-196) , MANUFACTURE(72657-196) , PACK(72657-196)

Revised: 12/2024

GLENMARK THERAPEUTICS INC., USA