

POLYETHYLENE GLYCOL 3350- polyethylene glycol 3350 powder, for solution
Cardinal Health 107, LLC

Major 44-726

Active ingredient (in each dose)

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 need to use a laxative for longer than 1 week
- you get diarrhea

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 (1-800-222-1222) right away.

Directions

- **do not take more than directed unless advised by your doctor**
- adults and children 17 years of age and older:
 - stir and dissolve one packet of powder (17 g) 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° to 25°C (68° to 77°F)
- tamper-evident: do not use if foil is open or broken

Inactive ingredients

none

Questions or comments?

(800) 616-2471

Distributed By:

Cardinal Health

Dublin, OH 43017

L56089710520

Principal Display Panel

PEG3350

Polyethylene Glycol 3350

Powder for Oral Solution, Osmotic Laxative

5 -Packets NET WT 0.5 OZ (17 g) EACH



NDC 55154-8090-5

T119

PEG3350

Polyethylene Glycol 3350

Powder for Oral Solution, Osmotic Laxative

5-Packets NET WT 0.5 OZ (17 g) EACH

Compare to MiralAX® active ingredient*

Once-Daily Doses

• Relieves Occasional Constipation (Irregularity) • Softens Stool

• Dissolves in Any Beverage • Sugar Free

Drug Facts

Active ingredient (in each dose)

Purpose

Polyethylene Glycol 3350, 17 g

Osmotic Laxative

Use

■ relieves occasional constipation (irregularity)

■ generally produces a bowel movement in 1 to 3 days

Inactive ingredients none

Directions

■ do not take more than directed unless advised by your doctor

■ adults and children 17 years of age and older:

■ stir and dissolve one packet of powder (17 g) 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

■ STORAGE store at 20° to 25°C (68° to 77° F)

■ tamper-evident: do not use if foil is open or broken

WARNING: This Unit Dose package is not child resistant and is intended for Institutional Use Only.

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 (1-800-222-1222) right away.

Distributed by MAJOR® PHARMACEUTICALS

17177 N Laurel Park Drive, Suite 233 Livonia, MI 48152

Product of India

*This product is not manufactured or distributed by Bayer HealthCare LLC, owner of the registered trademark MiralAX®.

Questions or comments? (800) 616-2471

Distributed by Cardinal Health

Dublin, OH 43017

L58089710520

LOT #: XXXXXXXXXX EXP. DATE: XX/XX/XX

POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-8090(NDC:0904-6931)
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
1	NDC:55154-8090-5	5 in 1 BAG	06/30/2019
1		17 g in 1 POUCH; Type 0: Not a Combination Product	
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203928	06/30/2019	

Labeler - Cardinal Health 107, LLC (118546603)