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

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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

L56118351223

### **Principal Display Panel**

PEG3350

Polyethylene Glycol 3350

Powder for Oral Solution, Osmotic Laxative

5 - Packets Net Wt. 0.5 OZ (17 g) Each



U120

NDC 55154-8091-5

#### 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 Unflavored

Drug Facts

Active ingredient (in each dose)

Polyethylene Glycol 3350, 17 g

Purpose Osmotic Laxative

Inactive ingredients none

#### Use

- relieves occasional constipation (irregularity)
- generally produces a bowel movement in 1 to 3 days

#### Directions

- do not take more than directed unless advised by your doctor
- adults and children 17 years of age and older:
  - use once a day
  - stir and dissolve one packet of powder (17 g) 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

- STORAGE: store at 20° 25°C (68° 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 right away.

Distributed by MAJOR® PHARMACEUTICALS

Indianapolis, IN 46268

www.majorpharmaceuticals.com

Product of India

\*This product is not manufactured or distributed by

Bayer HealthCare LLC,

owner of the registered trademark MiraLAX®.

Questions or comments? 1-800-616-2471

KR/DRUGS/KTK/25/415/98

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Dublin, OH 43017

L56118351223

Lot: Exp:

### **POLYETHYLENE GLYCOL 3350**

polyethylene glycol 3350 powder, for solution

#### **Product Information**

**Product Type** 

HUMAN OTC DRUG

Item Code (Source)

NDC:55154-8091(NDC:0904-6931)

#### **Route of Administration**

ORAL

### **Active Ingredient/Active Moiety**

ı	Active ingredient/Active Molety				
	Ingredient Name	<b>Basis of Strength</b>	Strength		
l	<b>POLYETHYLENE GLYCOL 3350</b> (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	Packaging					
# Item Code	Package Description	Marketing Start Date	Marketing End Date			
1 NDC:55154- 8091-5	5 in 1 BAG	06/30/2019				
1	17 g in 1 POUCH; Type 0: Not a Combination Product					

Marketing I	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)

Revised: 2/2024 Cardinal Health 107, LLC