

**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 get diarrhea
- you need to use a laxative for longer than 1 week
- you have rectal bleeding or your nausea, bloating, cramping or abdominal pain gets worse. These may be signs of a serious condition.

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**
- 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

- store at 20° - 25°C (68° - 77°F)
- tamper-evident: do not use if foil is open or broken

Inactive ingredients

none

Questions or comments?

1-800-616-2471

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Overbagged with 5 x 0.5 OZ (17 g) packets in each bag, NDC 55154-8091-5

WARNING: This Unit Dose package is not child resistant and is Intended for Institutional Use Only. Keep this and all drugs out of the reach of children.

Rev. 03/22	M-17	Re-order No. 701066
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Distributed By:

Cardinal Health

Dublin, OH 43017

L56118351223

Principal Display Panel

NDC 55154-8091-5

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

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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

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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

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:55154-8091-5	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)