POLYETHYLENE GLYCOL (3350)- polyethylene glycol (3350) powder, for solution

Mylan Institutional Inc.

Drug Facts

Active ingredient (in each dose)

Polyethylene Glycol 3350, USP, 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 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 the contents of one pouch (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 no 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° to 25°C (68° to 77°F)
- tamper-evident: do not use if pouch is damaged or torn
- for institutional use only

Inactive ingredients

none

Questions or comments?

1-877-4-INFO-RX (1-877-446-3679)

Manufactured for:

Mylan Institutional Inc.

Rockford, IL 61103 U.S.A.

MII306-30:RX

Principal Display Panel

NDC 51079-306-30

Polyethylene Glycol 3350, USP Powder for Solution,

Osmotic Laxative

- Relieves Occasional Constipation/Irregularity
- Softens Stool
- Unflavored
- Powder
- Grit Free
- Sugar Free
- Dissolves in Any Beverage

This carton contains 30 single-dose pouches. Each pouch contains 17 grams of polyethylene glycol 3350, USP powder.

For institutional use only. 30 Single-Dose Pouches



POLYETHYLENE GLYCOL (3350) polyethylene glycol (3350) powder, for solution Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:51079-306
Route of Administration	ORAL		

Active Ingredient/Active Moiety				
Ingredient Name	Basis of Strength	Strength		

POLYETHYLENE GLYCOL 3500 (UNII: FVS1AZD90Y) (POLYETHYLENE GLYCOL	POLYETHYLENE	17 g
3500 - UNII:FVS1AZD90Y)	GLYCOL 3500	in 17 g

Product Characteristics			
Color	white	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

I	Packaging			
4	tem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:51079-306- 30	30 in 1 CARTON	10/12/2009	
1	NDC:51079-306- 01	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	ANDA078915	10/12/2009	

Labeler - Mylan Institutional Inc. (039615992)

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