

POLYETHYLENE GLYCOL 3350 NF- polyethylene glycol 3350 powder, for solution

Woodward Pharma Services LLC

Polyethylene Glycol 3350 powder, for solution

Drug Facts

Active ingredient

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 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:
 - stir and dissolve one packet 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° - 25°C (68° - 77°F)
- tamper-evident: do not use if printed foil pouch is open or broken

Inactive ingredient

none

Questions or comments?

1-888-514-4727

PRINCIPAL DISPLAY PANEL

NDC 69784-180-01

Compare to MiraLAX®

Original Prescription Strength

PEG3350

Polyethylene Glycol 3350

Powder for Oral Solution, Osmotic Laxative

Relieves Occasional Constipation (irregularity)

Softens Stool

NET WT 0.5 OZ (17gm)

1 DOSE

To Open: Fold corner and tear at notch
Use scissors if necessary



NDC 69784-180-01

Compare to
MiraLAX® *

Original Prescription Strength

PEG3350

***Polyethylene Glycol 3350
Powder for Oral Solution,
Osmotic Laxative***

- **Relieves Occasional Constipation (irregularity)**
- **Softens Stool**



WOODWARD PHARMA

NET WT 0.5 OZ (17gm)

1 DOSE

PRINCIPAL DISPLAY PANEL

NDC 69784-180-14

Compare to MiraLAX®

Original Prescription Strength

PEG3350

Polyethylene Glycol 3350

Powder for Oral Solution, Osmotic Laxative


Relieves Occasional Constipation (irregularity)

Softens Stool

14 ct Unit-Dose Packets

0.5 OZ (17 gm) each

WOODWARD PHARMA



non-varnished area for coding

14 ct Unit-Dose Packets
0.5 OZ (17 gm) each

• Relieves Occasional Constipation (irregularity) • Softens Stool

Polyethylene Glycol 3350 Powder for Oral Solution, Osmotic Laxative

PEG3350

Original Prescription Strength

Compare to MiraLAX® *

NDC 69784-180-14

NDC 69784-180-14

Compare to MiraLAX® *

Original Prescription Strength

PEG3350

Polyethylene Glycol 3350
Powder for Oral Solution,
Osmotic Laxative

• Relieves Occasional

Drug Facts	
Active ingredient	Purpose
Polyethylene Glycol 3350, 17 g	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 as soon as possible. Poison Control: 1-800-498-0999	

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:
• stir and dissolve one packet (17g) 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° - 25°C (68° - 77°F) • tamper-evident:
do not use if printed foil pouch is open or broken

Inactive ingredients none

Questions or comments?
1-888-514-4727

Dissolves in Any Beverage Sugar free
*This product is not manufactured or distributed by
MSD Consumer Care, Inc., the distributor of MiraLAX®
Distributed by: Woodward Pharma Services LLC
Birmingham, MI 48009



Constipation (irregularity)
• **Softens Stool**

14ct Unit-Dose Packets
0.5 OZ (17 gm) each



WOODWARD PHARMA

POLYETHYLENE GLYCOL 3350 NF

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69784-180(NDC:11534-180)
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	Score	
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Shape		Size		
Flavor		Imprint Code		
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:69784-180-14	14 in 1 CARTON	06/06/2018	
1	NDC:69784-180-01	17 g in 1 POUCH; Type 0: Not a Combination Product		
2	NDC:69784-180-30	30 in 1 CARTON	06/06/2018	
2	NDC:69784-180-01	17 g in 1 POUCH; Type 0: Not a Combination Product		
3	NDC:69784-180-10	100 in 1 CARTON	06/06/2018	
3	NDC:69784-180-01	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	ANDA206105		06/06/2018	

Labeler - Woodward Pharma Services LLC (080406260)

Registrant - Woodward Pharma Services LLC (080406260)

Establishment			
Name	Address	ID/FEI	Business Operations
Future Pak, Ltd.		087737672	repack(69784-180)

Revised: 7/2022

Woodward Pharma Services LLC