# POLYETHYLENE GLYCOL 3350 - polyethylene glycol 3350 powder, for solution Emcure Pharmaceuticals USA Inc.

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Drug Facts
Active ingredient (in each dose)
Polyethylene Glycol 3350, 17 g (cap filled to line)
Purpose
Osmotic Laxative

### **INDICATIONS & USAGE**

#### 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 of 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 or 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
- side effects occur. You may report side effects to FDA at **1-800-FDA-1088**

**If pregnant or breast-feeding,** ask a health professional before use.

**Keep out of the 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
- the bottle top is a measuring cap marked to contain 17 grams of powder when filled to the indicated line (white section in cap)
- adults and children 17 years of age and older:

- fill to top of white section in cap which is marked to indicate the correct dose (17g)
- stir and dissolve 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 foil seal under cap, printed with "SEALED for YOUR PROTECTION" is missing, open or broken

Inactive ingredients none

# Principal display panel

# Base panel

Polyethylene Glycol 3350 NF Powder for Solution, Osmotic Laxative

- Relieves Occasional Constipation (Irregularity)
- Softens Stools

NDC 14539-150-20 Original Prescription Strength Dissolves in Any Beverage 30 ONCE-DAILY DOSES Net Wt. 510 g

Polyethylene Glycol 3350 NF increases frequency of bowel movements and softens the stools.

Manufactured By:

Emcure Pharmaceuticals USA Inc.

21/B Cotters Lane

East Brunswick, NJ 08816, USA.

### Top panel

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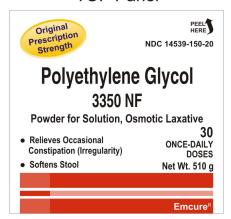
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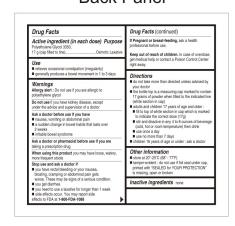
# Inactive ingredients none

#### **Base Panel** NDC 14539-150-20 Original Prescription Strength Dissolves in Any Beverage Polyethylene Glycol 3350 NF increases frequency of bowel movements and softens the stool. **Polyethylene Glycol** Manufactured by: Emcure Pharmaceuticals USA Inc. 21/B Cotters Lane East Brunswick, NJ 08816, USA. 3350 NF **Powder for Solution, Osmotic Laxative** 30 Relieves Occasional ONCE-DAILY Constipation (Irregularity) DOSES Softens Stool Net Wt. 510 g -OT:

# **TOP Panel**



# **Back Panel**



# **POLYETHYLENE GLYCOL 3350**

polyethylene glycol 3350 powder, for solution

Product Information				
Product Type	HUMAN PRESCRIPTION DRUG LABEL	Item Code (Source)	NDC:14539 - 150	
Route of Administration	ORAL	DEA Schedule		

Active Ingredient/Active Moiety			
Ingredient Name	Basis of Strength	Strength	
POLYETHYLENE GLYCOL 3350 (POLYETHYLENE GLYCOL 3350)	POLYETHYLENE GLYCOL 3350	17 g	

Product Characteristics			
Color	WHITE (Colorless upon dissolution)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

]	Packaging				
7	# Item Code	Package Description	Marketing Start Date	Marketing End Date	
	NDC:14539-150-20	30 in 1 BOTTLE			

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202071	09/28/2011	

# **Labeler** - Emcure Pharmaceuticals USA Inc. (189630168)

Establishment				
Name	Address	ID/FEI	Business Operations	
Emcure Pharmaceuticals USA Inc.		189630168	ANALYSIS(14539-150), MANUFACTURE(14539-150)	

Revised: 1/2013 Emcure Pharmaceuticals USA Inc.