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

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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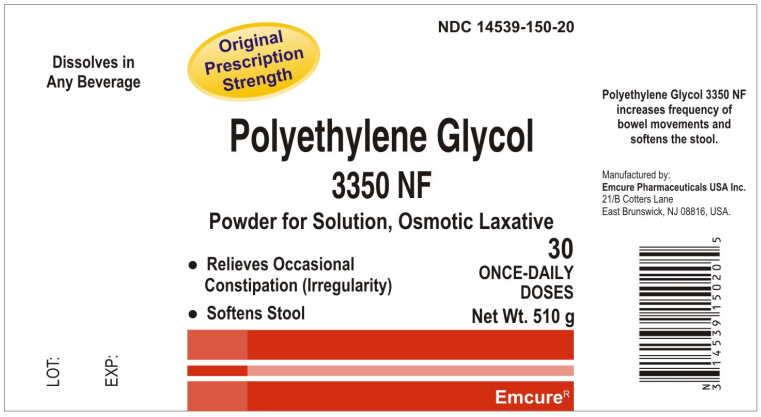
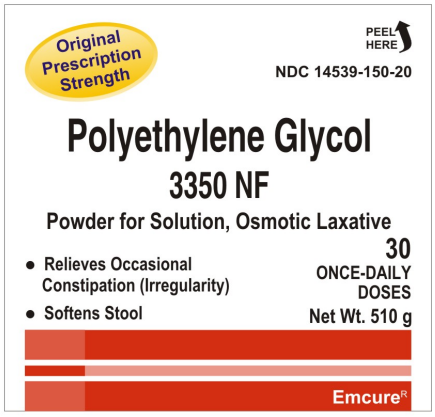
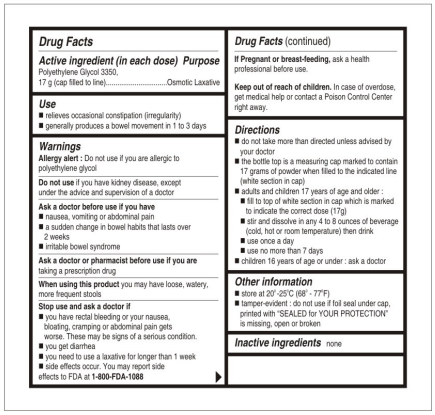


TOP Panel



Back Panel



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Inactive ingredients none

POLYETHYLENE GLYCOL 3350 polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**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 (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	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: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.