

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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Manufactured by:
Emcure Pharmaceuticals USA Inc.
2118 Cottlers Lane
East Brunswick, NJ 08816, USA.



LOT: _____

EXP: _____

Emcure[®]

TOP Panel

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Emcure[®]

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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		

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.