

**POLYETHYLENE GLYCOL 3350- polyethylene glycol 3350 powder, for solution**  
**Marlex Pharmaceuticals Inc**

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**Polyethylene Glycol 3350**

**MARLEX PHARMACEUTICALS, INC**

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**Polyethylene Glycol 3350 powder, for solution**

***Drug Facts***

***Active ingredient (in each dose)***

Polyethylene Glycol 3350, 17 g (cap filled to line)

***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 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**
- the bottle top is a measuring cap marked to contain 17 grams of powder when filled to the indicated line (clear section in cap)
- adults and children 17 years of age and older:
  - fill to top of clear section in cap which is marked to indicate the correct dose (17 g)
  - 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 ingredient***

none

***Questions or comments?***

1-800-FDA-1088

Manufactured for & Distributed by:

**Marlex Pharmaceuticals, Inc.**

New Castle, DE 19720

Rev. 04/19IT

**PRINCIPAL DISPLAY PANEL**

NDC 10135-0683-04

Polyethylene Glycol

3350

Powder for Solution, Osmotic Laxative

Net Wt 4.1 oz (119 g)

7 Once-Daily Doses

NDC 10135-0683-04

**MARLEX**  
PHARMACEUTICALS, INC.

**Polyethylene Glycol  
3350**

Powder for Solution, Osmotic Laxative

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

**Net Wt 4.1 oz (119 g)**

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

**7 Once-Daily Doses**

**Drug Facts**

**Active ingredient (in each dose)**  
Polyethylene Glycol 3350, 17 g (cap filled to line) ..... Osmotic Laxative

**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
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- 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

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Peel Here ▼

**PRINCIPAL DISPLAY PANEL**

NDC 10135-0683-08  
 Polyethylene Glycol  
 3350  
 Powder for Solution, Osmotic Laxative  
 Net Wt 8.3 oz (238 g)  
 14 Once-Daily Doses

NDC 10135-0683-08

**MARLEX**  
PHARMACEUTICALS, INC.

**Polyethylene Glycol  
3350**

Powder for Solution, Osmotic Laxative

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

**Net Wt 8.3 oz (238 g)**

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Polyethylene Glycol 3350, 17 g (cap filled to line) ..... Osmotic Laxative

**Purpose**  
..... Osmotic Laxative

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- you get diarrhea
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**Other information**  

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**Inactive ingredient** none

**Questions or comments?** 1-800-FDA-1088

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**PRINCIPAL DISPLAY PANEL**

NDC 10135-0683-12  
 Polyethylene Glycol  
 3350  
 Powder for Solution, Osmotic Laxative  
 Net Wt 17.9 oz (510 g)  
 30 Once-Daily Doses

NDC 10135-0683-12

**MARLEX**  
PHARMACEUTICALS, INC.

**Polyethylene Glycol  
3350**

**Powder for Solution, Osmotic Laxative**

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

**Net Wt 17.9 oz (510 g)**

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

**30 Once-Daily Doses**

**Drug Facts**

**Active ingredient (in each dose)**  
Polyethylene Glycol 3350, 17 g (cap filled to line) .....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.

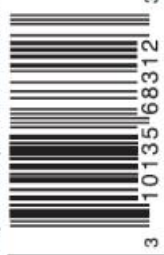
**Directions** ■ do not take more than directed unless advised by your doctor  
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**Inactive ingredient** none

**Questions or comments?** 1-800-FDA-1088

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## POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:10135-683
<b>Route of Administration</b>	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

<b>Color</b>	WHITE	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:10135-683-04	119 g in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2019	
2	NDC:10135-683-08	238 g in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2019	
3	NDC:10135-683-12	510 g in 1 BOTTLE; Type 0: Not a Combination Product	04/01/2019	

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA202071	04/01/2019	

**Labeler** - Marlex Pharmaceuticals Inc (782540215)

Revised: 5/2019

Marlex Pharmaceuticals Inc