

POLYETHYLENE GLYCOL 3350- polyethylene glycol 3350 powder, for solution
Padagis Israel Pharmaceuticals Ltd

Polyethylene Glycol 3350 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 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 (1-800-222-1222).

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:
 - use once a day
 - fill to top of white 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
- do not combine with starch-based thickeners used for difficulty swallowing
- ensure that the powder is fully dissolved before drinking
- do not drink if there are any clumps
- do not use 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 seal under cap is missing, open or broken

Inactive ingredients

none

Questions or comments?

1-800-719-9260

Principal Display Panel

Compare to MiraLAX® active ingredient

Polyethylene Glycol 3350

Powder for Solution

Osmotic Laxative

- Relieves Occasional Constipation/Irregularity

- Softens Stool

Unflavored Powder

Grit Free

NET WT 8.3 OZ (238 g)

14 Once-Daily Doses

NDC 45802-868-02

Compare to
MiraLAX[®] active ingredient*

Polyethylene Glycol 3350

Powder for Solution
Osmotic Laxative

- Relieves Occasional Constipation/Irregularity
- Softens Stool

Unflavored Powder
Grit Free

NET WT 8.3 OZ (238 g)
14 Once-Daily Doses



306E1 RT F8

← Peel Here

Polyethylene Glycol 3350 increases frequency of bowel movements and softens the stool.
Dissolves in Any Beverage

Drug Facts	
Active ingredient (in each dose)	Purpose
Polyethylene Glycol 3350, 17 g (cap filled to line).....	Osmotic Laxative
Use	
<ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 <ul style="list-style-type: none"> 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 	

3 45802-868-02 2

• Sugar Free

: 306E1 RT B7

Drug Facts (continued)

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 (1-800-222-1222).

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:
 - use once a day
 - fill to top of white 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
 - do not combine with starch-based thickeners used for difficulty swallowing
 - ensure that the powder is fully dissolved before drinking
 - do not drink if there are any clumps
 - do not use 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 seal under cap is missing, open or broken

Inactive ingredients none

Questions or comments? 1-800-719-9260

*This product is not manufactured or distributed by Bayer HealthCare LLC, distributor of MiraLAX®.
Distributed By Padagis
Allegan, MI 49010 • www.padagis.com

POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45802-868
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	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:45802-868-01	119 g in 1 BOTTLE; Type 0: Not a Combination Product	11/06/2009	
2	NDC:45802-868-03	510 g in 1 BOTTLE; Type 0: Not a Combination Product	11/05/2009	

3	NDC:45802-868-02	238 g in 1 BOTTLE; Type 0: Not a Combination Product	11/04/2009	
4	NDC:45802-868-66	14 in 1 CARTON	07/16/2018	
4		17 g in 1 PACKET; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090685	10/13/2009	

Labeler - Padagis Israel Pharmaceuticals Ltd (600093611)

Revised: 1/2023

Padagis Israel Pharmaceuticals Ltd