

MIRALAX- polyethylene glycol 3350 powder, for solution
Cardinal Health 107, LLC

MiraLAX®

Drug Facts

Active ingredient (in each dose) (Packet Only)

Polyethylene Glycol 3350, 17 g

Purpose

Osmotic Laxative, powder for Solution

Unflavored powder grit free

Each Packet contains one dose, net wt 0.5 oz (17g)

Mix-In Pax®

Travel Size

Relieves occasional constipation / irregularity

Softens stool

ONCE-DAILY DOSES

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 the reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.

This Unit dose package is not child resistant and is intended for Institutional Use Only. Keep this and all drugs out of the reach of children.

Directions (Packet Only)

- **do not take more than directed unless advised by your doctor**
- adults and children 17 years of age and older:
 - stir and dissolve one packet of powder (17 g) in any 4 to 8 ounces of beverage (cold, hot or room temperature) then drink
 - ensure that the powder is fully dissolved before drinking
 - do not drink if there are any clumps
 - 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 is open or broken
- Unflavored
- Sugar Free
- Dissolves in any Beverage

Inactive ingredients

none

Questions or comments?

1-800-MiraLAX (1-800-647-2529)

Bayer, the Bayer Cross, Mix-In Pax and MiraLAX are registered trademarks of Bayer.

Dist. By: Bayer HealthCare LLC

Whippany, NJ 07981

NeatPAX is a trademark owned by its respective owner.

Distributed by:

Cardinal Health

Dublin, OH 43017

L4532222-10124

L4532222-20124

Principal Display Panel

MiraLAX®

Polyethylene Glycol 3350,

Powder for Solution, Osmotic Laxative

6 Packets



P83

NDC 55154-5035-6

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Powder for Solution, Osmotic Laxative
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#1 DOCTOR RECOMMENDED BRAND

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Directions

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- adults and children 17 years of age and older:
 - use once a day
 - stir and dissolve one packet of powder (17 g) 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 no more than 7 days
- children 16 years of age or under: ask a doctor

STORAGE: Store at 20° - 25° C (68° - 77° F)

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07981

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Lot: Exp:

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MIRALAX

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:55154-5035(NDC:11523-7268)
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 (Colorless upon dissolution)	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55154-5035-6	6 in 1 BAG	02/23/2009	
1		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
NDA	NDA022015	02/23/2009	

Labeler - Cardinal Health 107, LLC (118546603)