

MIRALAX- polyethylene glycol 3350 powder, for solution
Bayer HealthCare LLC.

MiraLAX®

Drug Facts

Active ingredient (in each dose) (Bottle Only)

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

Purpose

Osmotic Laxative

Active ingredient (in each dose) (Packet Only)

Polyethylene Glycol 3350, 17 g

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 you 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

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 (Bottle Only)

- **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 no more than 7 days
- children 16 years of age or under: ask a doctor

Directions (Packet Only)

- **do not take more than directed unless advised by your doctor**
- 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 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

Questions or comments?

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

PRINCIPAL DISPLAY PANEL - 17 g × 20 Packet Carton

20

Single Doses

#1 DOCTOR RECOMMENDED BRAND

MiraLAX®

Polyethylene Glycol 3350, Powder for Solution, Osmotic Laxative

Mix-In Pax®

- Relieves Occasional Constipation/Irregularity
- Softens Stool

20

ONCE-DAILY DOSES

Bayer

Unflavored Powder Dissolves in ANY Beverage!

UNFLAVORED

POWDER

GRIT FREE

20 PACKETS

NET WT 0.5 OZ

(17g) EACH



PRINCIPAL DISPLAY PANEL - 17 g x 10 Packet Carton

10

Single Doses

#1 DOCTOR RECOMMENDED BRAND

MiraLAX®

Polyethylene Glycol 3350, Powder for Solution, Osmotic Laxative

Mix-In Pax®

- Relieves Occasional Constipation/Irregularity
- Softens Stool

10

ONCE-DAILY DOSES

Bayer

Unflavored Powder Dissolves in ANY Beverage!

UNFLAVORED
POWDER

GRIT FREE

10 PACKETS

NET WT 0.5 OZ

(17g) EACH



PRINCIPAL DISPLAY PANEL - 30 Dose (510 g) Bottle Label

Easy to Pour Bottle

#1 DOCTOR RECOMMENDED BRAND

MiraLAX®

Polyethylene Glycol 3350, Powder for Solution, Osmotic Laxative

UNFLAVORED

POWDER

GRIT FREE

- Relieves Occasional Constipation/Irregularity
- Softens Stool

Bayer

30 ONCE-DAILY DOSES
NET WT 17.9 OZ (510 g)





PRINCIPAL DISPLAY PANEL - Twinpack 2x34 Dose (578 g) Bottle Label

Twin Pack!

2 x 34 Doses

Easy to Pour Bottle

MiraLAX®

Polyethylene Glycol 3350, Powder for Solution, Osmotic Laxative

#1 DOCTOR RECOMMENDED BRAND

- Relieves Occasional Constipation/Irregularity
- Softens Stool

UNFLAVORED

POWDER

GRIT FREE

Bayer

34 ONCE-DAILY DOSES

NET WT 20.4 OZ (578 g)





MIRALAX

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	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:11523-7268-3	10 in 1 CARTON	02/01/2007	
1		17 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:11523-7268-8	24 in 1 CARTON	02/01/2007	
2		17 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:11523-7268-7	5 in 1 CARTON	02/01/2007	01/01/2015
3		17 g in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:11523-7268-4	765 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2007	
5	NDC:11523-7268-9	20 in 1 CARTON	02/01/2007	
5		17 g in 1 POUCH; Type 0: Not a Combination Product		
Marketing Information				
Marketing Category		Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA		NDA022015	02/01/2007	

MIRALAX			
polyethylene glycol 3350 powder, for solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11523-7234
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:11523-7234-1	17 g in 1 PACKET; Type 0: Not a Combination Product	02/01/2007	
2	NDC:11523-7234-2	119 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2007	
3	NDC:11523-7234-3	238 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2007	
4	NDC:11523-7234-4	510 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2007	
5	NDC:11523-7234-5	12 in 1 CARTON	02/01/2007	01/01/2012
5		17 g in 1 PACKET; Type 0: Not a Combination Product		
6	NDC:11523-7234-6	17 g in 1 PACKET; Type 0: Not a Combination Product	02/01/2007	
7	NDC:11523-7234-9	2 in 1 CELLO PACK	02/01/2007	01/01/2014
7		510 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA022015	02/01/2007	

MIRALAX

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:11523-7341
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:11523-7341-1	612 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	02/01/2007	
2	NDC:11523-7341-2	3 in 1 CARTON	02/01/2007	
2		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	02/01/2007	

MIRALAX				
polyethylene glycol 3350 powder, for solution				
Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:11523-4357
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:11523-4357-1	2 in 1 PACKAGE, COMBINATION	02/01/2007	01/01/2018

1		765 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
2	NDC:11523-4357-3	2 in 1 PACKAGE, COMBINATION	02/01/2007	
2		578 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product		
3	NDC:11523-4357-5	24 in 1 CARTON	05/01/2018	
3		17 g in 1 PACKET; Type 0: Not a Combination Product		
4	NDC:11523-4357-2	2 in 1 CARTON	02/01/2007	
4		20 in 1 CARTON		
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
NDA	NDA022015	02/01/2007	

Labeler - Bayer HealthCare LLC. (112117283)