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 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 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
 - $\circ~$ stir and dissolve one packet of powder (17 g) in any 4 to 8 ounces of beverage (cold, hot or room temperature) then drink
 - $\circ~$ do not combine with starch-based thickeners used for difficulty swallowing
 - ensure that the powder is fully dissolved before drinking
 - $\circ~$ do not drink if there are any clumps
 - \circ 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 \times 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 \times 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)



Drug Facts Drug Facts (continued) Keep out of reach of children. In case of overdose, get Active ingredient (in each dose) Purpose medical help or contact a Poison Control Center right away. Polyethylene Glycol 3350, 17 g (cap filled to line)... Osmotic Laxative Directions ■ do not take more than directed unless advised by Use your doctor ■ relieves occasional constipation (irregularity) ■ the bottle top is a measuring cap marked to contain generally produces a bowel movement in 1 to 3 days 17 grams of powder when filled to the indicated line (white section in cap) ■ adults and children 17 years of age and older: Warnings Allergy alert: Do not use if you are allergic to use once a day polyethylene glycol ■ fill to top of white section in cap which is marked to indicate the correct dose (17g) Do not use if you have kidney disease, except under the stir and dissolve in any 4 to 8 ounces of beverage advice and supervision of a doctor (cold, hot or room temperature) then drink Ask a doctor before use if you have do not combine with starch-based thickeners used nausea, vomiting or abdominal pain for difficulty swallowing a sudden change in bowel habits that lasts over ensure that the powder is fully dissolved before drinking do not drink if there are any clumps ■ irritable bowel syndrome do not use more than 7 days Ask a doctor or pharmacist before use if you are ■ children 16 years of age or under: ask a doctor taking a prescription drug Other information When using this product you may have loose, watery, ■ store at 20° - 25°C (68° - 77°F) more frequent stools tamper-evident do not use if foil seal under cap, Stop use and ask a doctor if printed with "SEALED for YOUR PROTECTION" is ■ you have rectal bleeding or your nausea, missing, open or broken bloating, cramping or abdominal pain gets worse. These may be signs of a serious condition. Inactive ingredients none you get diarrhea ■ you need to use a laxative for longer than 1 week Questions or comments? 1-800-MiraLAX (1-800-647-2529) If pregnant or breast-feeding, ask a health professional Sugar Free c00011207

MIRALAX

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		

P	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			
6	NDC:11523- 7268-5	850 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	05/30/2025		

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

MIRALAX

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	17 g in 17 g		

Product Characteristics		
Color	white (Colorless upon dissolution)	Score
Shape		Size
Flavor		Imprint Code
Contains		

P	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

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			

P	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

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)

Revised: 7/2025 Bayer HealthCare LLC.