MIRALAX- polyethylene glycol 3350 powder, for solution ASCLEMED USA INC.

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 useif 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
 - 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
 - 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

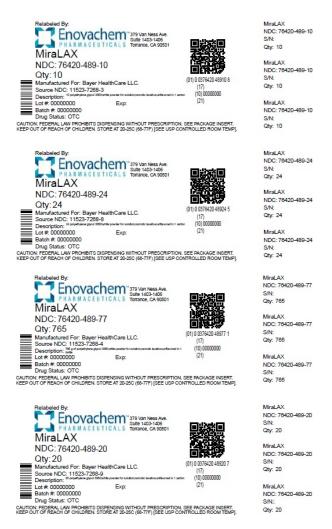
Inactive ingredients

none

Questions or comments?

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

PRINCIPAL DISPLAY PANEL



Relabeled By:

Enovacinem 379 Van Ness Ave.
Dufie 1403-1406
PHARMACEUTICALS Torrance, CA 90901

MiraLAX

NDC: 76420-489-85

Otty: 850

Manufactured For: Bayer HealthCare LLC.

(07) 00378-20148985

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MIRALAX

polyethylene glycol 3350 powder, for solution

Product Information Product Type HUMAN OTC DRUG Item Code (Source) NDC:76420-489(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:76420- 489-10	10 in 1 CARTON	10/14/2025	
1		17 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:76420- 489-24	24 in 1 CARTON	10/14/2025	
2		17 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:76420- 489-77	765 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/14/2025	
4	NDC:76420- 489-20	20 in 1 CARTON	10/14/2025	
4		17 g in 1 POUCH; Type 0: Not a Combination Product		
5	NDC:76420- 489-85	850 g in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	10/14/2025	

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

Labeler - ASCLEMED USA INC. (059888437)

Establishment				
Name	Address	ID/FEI	Business Operations	
ASCLEMED USA INC. DBA ENOVACHEM		059888437	relabel(76420-489)	

Revised: 10/2025 ASCLEMED USA INC.