

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

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**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

Relabeled By:  
  
MiraLAX  
NDC: 76420-489-10  
Qty: 10

379 Van Ness Ave.  
Suite 1403-1405  
Torrance, CA 90501

  
(01) 0 0376420 48910 8  
(17)  
(10) 00000000  
(21)


Manufactured For: Bayer HealthCare LLC.  
Source NDC: 11523-7268-3  
Description: 10 g of polyethylene glycol 3350 powder for solution (orally administered in 1 carton)  
Lot #: 00000000      Exp:  
Batch #: 00000000  
Drug Status: OTC

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].


MiraLAX  
NDC: 76420-489-10  
S/N:  
Qty: 10

MiraLAX  
NDC: 76420-489-10  
S/N:  
Qty: 10

MiraLAX  
NDC: 76420-489-10  
S/N:  
Qty: 10

Relabeled By:  
  
MiraLAX  
NDC: 76420-489-85  
Qty: 850

379 Van Ness Ave.  
Suite 1403-1405  
Torrance, CA 90501

  
(01) 0 0376420 48985 6  
(17)  
(10) 00000000  
(21) -----


Manufactured For: Bayer HealthCare LLC.  
Source NDC: 11523-7268-5  
Description: 765 g of polyethylene glycol 3350 powder for solution (orally administered in 1 bottle)  
Lot #: 00000000      Exp:  
Batch #: 00000000  
Drug Status: OTC

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].


MiraLAX  
NDC: 76420-489-85  
S/N:  
Qty: 850

MiraLAX  
NDC: 76420-489-85  
S/N:  
Qty: 850

MiraLAX  
NDC: 76420-489-85  
S/N:  
Qty: 850

Relabeled By:  
  
MiraLAX  
NDC: 76420-489-24  
Qty: 24

379 Van Ness Ave.  
Suite 1403-1405  
Torrance, CA 90501

  
(01) 0 0376420 48924 5  
(17)  
(10) 00000000  
(21)


Manufactured For: Bayer HealthCare LLC.  
Source NDC: 11523-7268-8  
Description: 24 g of polyethylene glycol 3350 powder for solution (orally administered in 1 carton)  
Lot #: 00000000      Exp:  
Batch #: 00000000  
Drug Status: OTC

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].


MiraLAX  
NDC: 76420-489-24  
S/N:  
Qty: 24

MiraLAX  
NDC: 76420-489-24  
S/N:  
Qty: 24

MiraLAX  
NDC: 76420-489-24  
S/N:  
Qty: 24

Relabeled By:  
  
MiraLAX  
NDC: 76420-489-77  
Qty: 765

379 Van Ness Ave.  
Suite 1403-1405  
Torrance, CA 90501

  
(01) 0 0376420 48977 1  
(17)  
(10) 00000000  
(21)


Manufactured For: Bayer HealthCare LLC.  
Source NDC: 11523-7268-4  
Description: 765 g of polyethylene glycol 3350 powder for solution (orally administered in 1 bottle)  
Lot #: 00000000      Exp:  
Batch #: 00000000  
Drug Status: OTC

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].


MiraLAX  
NDC: 76420-489-77  
S/N:  
Qty: 765

MiraLAX  
NDC: 76420-489-77  
S/N:  
Qty: 765

MiraLAX  
NDC: 76420-489-77  
S/N:  
Qty: 765

Relabeled By:  
  
MiraLAX  
NDC: 76420-489-20  
Qty: 20

379 Van Ness Ave.  
Suite 1403-1405  
Torrance, CA 90501

  
(01) 0 0376420 48920 7  
(17)  
(10) 00000000  
(21)

Manufactured For: Bayer HealthCare LLC.  
Source NDC: 11523-7268-9  
Description: 20 g of polyethylene glycol 3350 powder for solution (orally administered in 1 carton)  
Lot #: 00000000      Exp:  
Batch #: 00000000  
Drug Status: OTC

CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION. SEE PACKAGE INSERT.  
KEEP OUT OF REACH OF CHILDREN. STORE AT 20-25C (68-77F) [SEE USP CONTROLLED ROOM TEMP].

MiraLAX  
NDC: 76420-489-20  
S/N:  
Qty: 20

MiraLAX  
NDC: 76420-489-20  
S/N:  
Qty: 20

MiraLAX  
NDC: 76420-489-20  
S/N:  
Qty: 20

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			

<b>Color</b>	white (Colorless upon dissolution)	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

### 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)