

CLEARLAX- polyethylene glycol 3350 powder, for solution
STRATEGIC SOURCING SERVICES LLC

SUNMARK PEG

Active ingredient (in each dose)

Polyethylene Glycol 3350, 17 grams (cap filled to the indicated "17 GRAMS" line)

Purpose

Laxative

Uses

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

Directions

- **do not take more than directed unless advised by your doctor**
- the bottle top is a measuring cup marked to contain 17 grams of powder when filled

to the indicated "17 GRAMS" line

- adults and children 17 years of age and older:
 - fill to indicated "17 GRAMS" line in cap which is marked to indicate the correct dose 17 grams
- stir and dissolve in any 4 to 8 ounces of beverage (cold, hot or room temperature) then drink
- use once a day
- use no more than 7 days
- children 16 years of age or younger: 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

For serious adverse events call:

1-888-710-0006

Package label

The image shows the product packaging for Sunmark Clearlax, which is a powder for solution. The packaging is blue and purple, with the Sunmark logo at the top left. The text on the packaging includes "COMPARE TO MIRALAX® ACTIVE INGREDIENT*", "NDC 49348-143-92", "clearlax®", "Polyethylene Glycol 3350 Powder For Solution, Osmotic Laxative", "Relieves occasional constipation/irregularity Softens stool • Grit free", "UNFLAVORED POWDER", "GLUTEN FREE", "30 ONCE-DAILY DOSES", and "NET WT 17.9 OZ (510 g)".

Below the packaging is a barcode with the number 10939 78944 0. To the right of the barcode is a box for "Lot No.:" and "Exp. Date:". Above the barcode is the text "MEKESON" and "Another Quality Product Distributed By McKesson One Post Street San Francisco, CA 94104 Money Back Guarantee Please visit us at www.sunmarkbrand.com".

At the top right of the label area, it says "Sugar-Free *This product is not manufactured or distributed by MSD Consumer Care, Inc., distributor of MiraLAX® Made in USA".

Below the barcode is a box for "Laxative Polyethylene Glycol 3350 increases the frequency of bowel movements and softens the stool Dissolves in Any Beverage".

At the bottom right of the label area is a table with the following information:

Drug Facts		Drug Facts (continued)	
Active ingredient (in each dose) Polyethylene Glycol 3350, 17 grams (cap filled to the indicated "17 GRAMS" line)	Purpose Laxative	Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.	
Use <ul style="list-style-type: none">relieves occasional constipation (irregularity)generally produces a bowel movement in 1 to 3 days	Warnings <p>Allergy alert: Do not use if you are allergic to polyethylene glycol.</p> Do not use if you have kidney disease, except under the advice and supervision of a doctor.	Directions <ul style="list-style-type: none">do not take more than directed unless advised by your doctorthe bottle cap is a measuring cup marked to contain 17 grams of powder when filled to the indicated "17 GRAMS" lineadults and children 17 years of age and older:<ul style="list-style-type: none">fill to indicated "17 GRAMS" line in cap, which is marked to indicate the correct dose 17 gramsstir and dissolve in any 4 to 8 ounces of beverage (cold, hot or room temperature) then drinkuse once a dayuse no more than 7 dayschildren 16 years of age or younger: ask a doctor	
Ask a doctor before use if you have <ul style="list-style-type: none">nausea, vomiting, or abdominal paina sudden change in bowel habits that lasts over 2 weeksirritable 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 <ul style="list-style-type: none">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.	Other information <ul style="list-style-type: none">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	
		For serious adverse events call: 1-888-710-0006	

Sunmark

compare to miralax active ingredient*

NDC 49348-143-92

clearlax

polyethylene glycol 3350

powder for solution, osmotic laxative
relieves occasional constipation /irregularity
Softens stool grit free
unflavored powder
gluten free
30 once-daily doses
net wt 17.9 oz (510 g)

CLEARLAX

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:49348-143
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	Score	
Shape		Size	
Flavor		Imprint Code	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:49348-143-70	238 g in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2016	
2	NDC:49348-143-92	510 g in 1 BOTTLE; Type 0: Not a Combination Product	07/01/2016	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090812	07/01/2016	

Labeler - STRATEGIC SOURCING SERVICES LLC (116956644)

Registrant - Geri-Care Pharmaceutical Corp (611196254)

Revised: 7/2021

STRATEGIC SOURCING SERVICES LLC