

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 displays the packaging for Sunmark Clearlax. On the left is the front of a 30-ounce bottle, which is purple and blue. It features the Sunmark logo and text: "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)".

In the center is a barcode with the number "10939 78944" and "0" on either side. 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". Above this is "Sugar-Free *This product is not manufactured or distributed by MSD Consumer Care, Inc., distributor of MiraLAX® Made in USA". Below the barcode is "Lot No.:" and "Exp. Date:" with a blank box for the date.

On the right is a "Drug Facts" label. At the top, it says "Laxative Polyethylene Glycol 3350 increases the frequency of bowel movements and softens the stool" and "Dissolves in Any Beverage". The label is divided into sections: "Drug Facts", "Drug Facts (continued)", "Other information", and "For serious adverse events call: 1-888-710-0006".

Drug Facts	Drug Facts (continued)
Active ingredient (In each dose) Polyethylene Glycol 3350, 17 grams (cap filled to the indicated "17 GRAMS" line) Laxative	Purpose Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away.
Use ■ relieves occasional constipation (irregularity) ■ generally produce a bowel movement in 1 to 3 days	Directions ■ do not take more than directed unless advised by your doctor ■ the bottle cap 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
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	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.
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 dizziness ■ you need to use a laxative for longer than 1 week if pregnant or breast-feeding, ask a health professional before use.	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)