

POLYETHYLENE GLYCOL 3350 - polyethylene glycol 3350 powder, for solution
CHAIN DRUG MARKETING ASSOCIATION, INC.

Polyethylene Glycol 3350 Powder for Oral Solution, 17 g

Active ingredient (in each dose)

Polyethylene Glycol 3350, 17 g (cap filled to line)

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 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 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 difficult 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° to 25°C (68° to 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?

call **1-888-375-3784**

PRINCIPAL DISPLAY PANEL

Polyethylene glycol 3350 powder for oral solution bottle label 238g

Front Label

Top Layer	Top Layer Back	Second Layer
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NDC 83324-002-08

*Compare to the active ingredient in MiraLax®.

Oral Laxative Powder Solution

Polyethylene Glycol 3350

Osmotic Laxative

Relieves Occasional Constipation/Irregularity
Softens Stool
Unflavored Powder
Grit Free
Sugar free

14 Once-Daily Doses NET WT 8.3 OZ (238 g)

Drug Facts

Active ingredient (in each dose) Purpose
Polyethylene Glycol 3350, 17 g
(cap filled to line).....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

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Drug Facts (continued)

■ 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.

Please see back label for continued Drug Facts 2

Back Label

Top Layer	Top Layer Back	Second Layer
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Polyethylene Glycol 3350 Powder for Oral Solution increases frequency of bowel movements and softens the stool.

*This product is not manufactured or distributed by Bayer Healthcare LLC, distributor of MiraLax®.

- Dissolves in any Beverage
- Sugar Free

Mfg. Lic. No.: 24/MD/TS/2016/F/G

Distributed by CDMA, Inc.
Novi, MI 48375
www.qualitychoice.com
Questions: 800-935-2362

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Drug Facts (continued)

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

Directions
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■ the bottle top is a measuring cap marked to contain 17 grams of powder when filled to the indicated line (white section in cap)
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 ■ do not combine with starch-based thickeners used for difficulty swallowing

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Drug Facts (continued)

- 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° to 25°C (68° to 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?
call 1-888-375-3784

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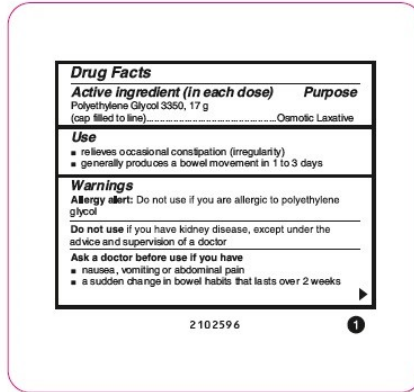
Polyethylene glycol 3350 powder for oral solution bottle label 510g

Front Label

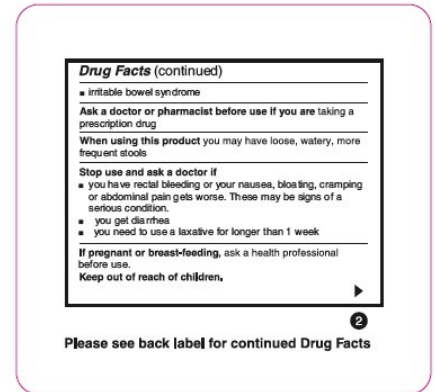
Top Layer



Top Layer Back



Second Layer

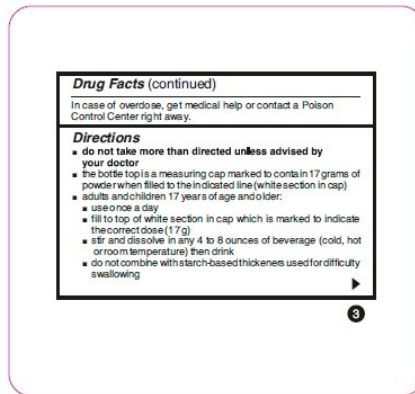


Back Label

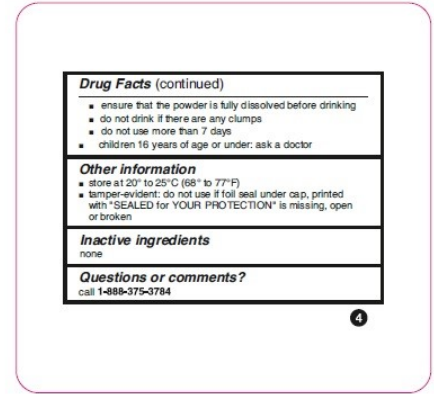
Top Layer



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Second Layer



POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:83324-002
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:83324-002-08	238 g in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	
2	NDC:83324-002-16	510 g in 1 BOTTLE; Type 0: Not a Combination Product	03/01/2024	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214990	03/01/2024	

Labeler - CHAIN DRUG MARKETING ASSOCIATION, INC. (011920774)

Establishment

Name	Address	ID/FEI	Business Operations
Annora Pharma Private Limited		650980746	analysis(83324-002) , manufacture(83324-002)

Revised: 3/2024

CHAIN DRUG MARKETING ASSOCIATION, INC.