

**POLYETHYLENE GLYCOL 3350, NF POWDER FOR SOLUTION, LAXATIVE-
polyethylene glycol 3350, nf powder for solution, laxative powder, for
solution**

Pharmaceutica North America, Inc.

PEG 3350

Drug Facts

ActiveIngredient (in each dose)

Polyethylene Glycol 3350, 17 g (cap filled to the top)

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.(1-800-222-1222)

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 the top of white section in cap which is marked to indicate the correct dose (17g)
 - 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 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?

1-888-788-6472

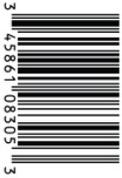
Manufactured for :

Pharmaceutica North America, Inc., Glendale, CA 912050.

Product label

NDC 45861-083-05

Tamper-evident: do not use if foil seal under cap printed with "SEALED for YOUR PROTECTION" is missing, open or broken.



Polyethylene Glycol 3350

OSMOTIC LAXATIVE

Relieves Occasional Constipation (Irregularity)
Softens Stool

UNFLAVORED POWDER | SUGAR FREE

NET WT 8.39 OZ 238G



Drug Facts

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(in each dose)
Polyethylene Glycol 3350,
17 grams (cap filled
to the top) 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 (1-800-222-1222).

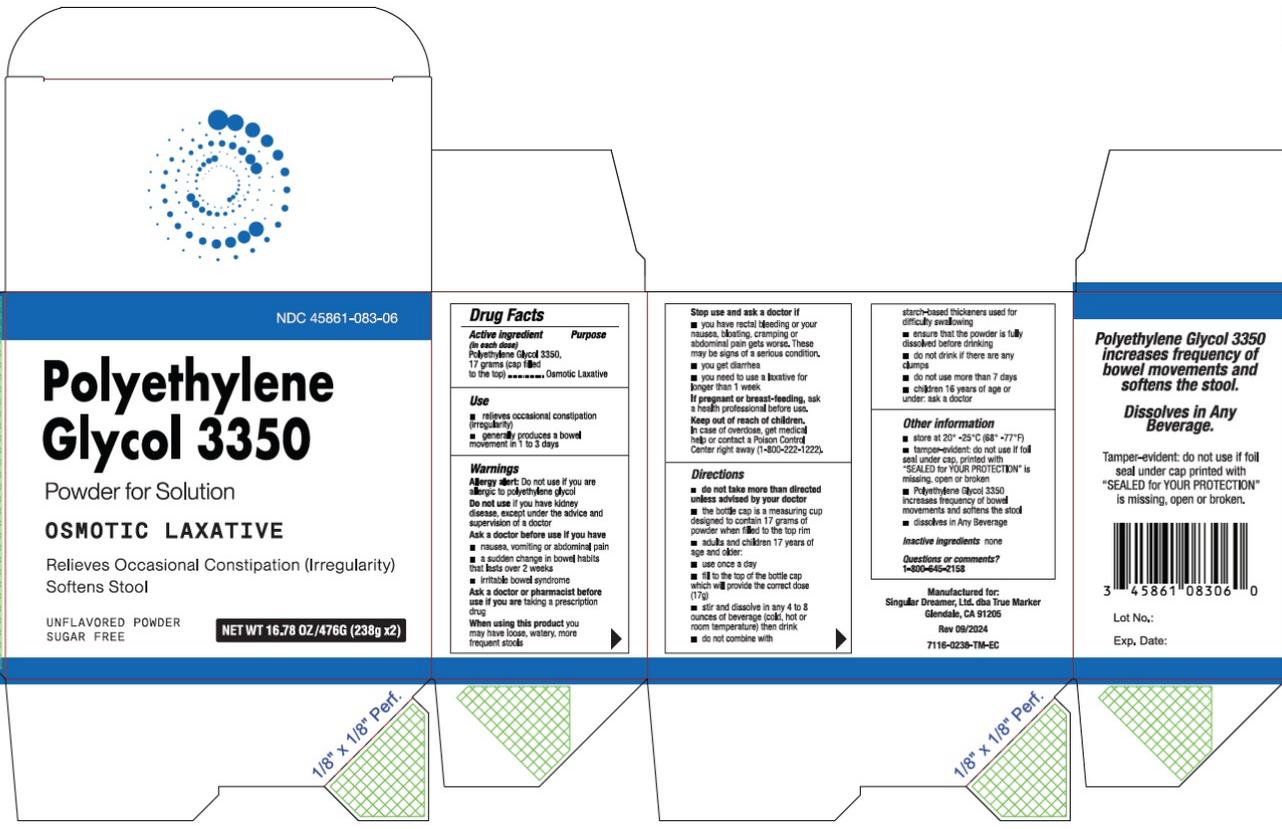
Directions
■ do not take more than directed unless advised by your doctor
■ the bottle cap is a measuring cup designed to contain 17 grams of powder when filled to the top rim
■ adults and children 17 years of age and older:
■ use once a day
■ fill to the top of the bottle cap which will provide the correct dose (17g)
■ 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 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
■ Polyethylene Glycol 3350 increases frequency of bowel movements and softens the stool
■ dissolves in Any Beverage

Inactive ingredients none
Questions or comments?
1-800-645-2158

Manufactured for:
Pharmaceutical North America,
Glendale, CA 91205
Tel.: 888-788-6472



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POLYETHYLENE GLYCOL 3350, NF POWDER FOR SOLUTION, LAXATIVE			
polyethylene glycol 3350, nf powder for solution, laxative powder, for solution			
Product Information			
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:45861-083
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 1 d

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:45861-083-05	238 d in 1 BOTTLE; Type 0: Not a Combination Product	02/10/2025	
2	NDC:45861-083-06	2 in 1 BOX	02/10/2025	
2		476 d in 1 BOTTLE; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090812	02/10/2025	

Labeler - Pharmaceutica North America, Inc. (962739699)

Revised: 3/2025

Pharmaceutica North America, Inc.