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

Pharmaceutica North America, Inc.

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**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 youare

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 orcomments?**

#### 1-888-788-6472

Manufactured for:

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

#### Product label



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# **Polyethylene** Glycol 3350

#### OSMOTIC LAXATIVE

NDC 45861-083-05

Relieves Occasional Constipation (Irregularity) Softens Stool

UNFLAVORED POWDER | SUGAR FREE

**NET WT 8.39 OZ 238G** 

#### Drug Facts

Active ingredient (in each dose) Polyethylene Glycol 3350, 17 grams (cap filled to the top) ............. Osmo

- generally produces a bowel movement in 1 to 3 days

Warnings
Allergy alert: Do not use if you are allergic to polyethylene plycol
Do not use if you have lidering or additionable of a discose, except under the advice and supervision of a discotor before use if you have
a nausea, vomiting or abdominal pain
a sudden change in bowel habits that lasts over 2 weeks
in irrable bowel syndrome
Ask a doctor or pharmacist before

- 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

- you have rectal bleeding or your nausea, bloating, cramping or abdominal pain gets worse. These may be signs of a serious condition.

Directions

 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. In pregnant or preast-reeding, 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).

 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:

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

#### Other information

#### store at 20° -25°C (68° -77°F)

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

- store at 20"-25" (188"-77")
   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

Questions or comme 1-800-645-2158

Pharmaceutica North An Glendale, CA 91205

Tel.: 888-788-6472

# 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 highen 16 years of age or under: ask a doctor Drug Facts Stop use and ask a doctor if NDC 45861-083-06 Active ingredien. (in each dose) Polyethylene Glycol 3350, 17 grams (cap filled Polyethylene Glycol 3350 increases frequency of bowel movements and softens the stool. Polyethylene Glycol 3350 Dissolves in Any Beverage. generally produces a bowel movement in 1 to 3 days 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, copen or broken Warnings Alergy after 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 in rauses, vomitting or abdominat plan a suddom change in bowel palse that fasts over 2 weeks in intuities bowel syndrome. Tamper-evident: do not use if foil seal under cap printed with "SEALED for YOUR PROTECTION" Powder for Solution **OSMOTIC LAXATIVE** Relieves Occasional Constination (Irregularity) Softens Stool Manufactured for: Dreamer, Ltd. dba True Mari Glendale, CA 91205 UNFLAVORED POWDER SUGAR FREE When using this product you may have loose, watery, more Exp. Date:

# POLYETHYLENE GLYCOL 3350, NF POWDER FOR SOLUTION, **LAXATIVE**

polyethylene glycol 3350, nf powder for solution, laxative powder, for solution

#### **Product Information HUMAN OTC DRUG** NDC:45861-083 **Product Type** Item Code (Source) **Route of Administration ORAL**

Active Ingredient/Active Moiety				
Ingredient Name	<b>Basis of Strength</b>	Strength		
<b>POLYETHYLENE GLYCOL 3350</b> (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				

P	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	02/10/2020		
2	NDC:45861-083- 06	2 in 1 BOX	02/10/2020		
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	02/10/2020		

# Labeler - Pharmaceutica North America, Inc. (962739699)

Revised: 2/2025 Pharmaceutica North America, Inc.