

**POLYETHYLENE GLYCOL 3350 - polyethylene glycol 3350 powder, for solution**  
**Camber Consumer Care Inc**

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**Polyethylene Glycol 3350 Powder for Oral Solution, 17 g**

**ACTIVE INGREDIENT (IN EACH DOSE)**

**(Bottle Only)**

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

**(Packet Only)**

Polyethylene Glycol 3350, 17 g

**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**

### **(Bottle Only)**

- **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

### **(Packet Only)**

- **do not take more than directed unless advised by your doctor**
- adults and children 17 years of age and older:

- use once a day
- stir and dissolve one packet of powder (17 g) 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 **1-888-588-1418**.

## **PRINCIPAL DISPLAY PANEL**

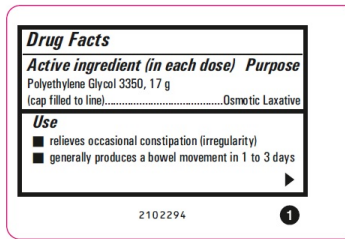
Polyethylene glycol 3350 powder for oral solution bottle label

# Front Labels

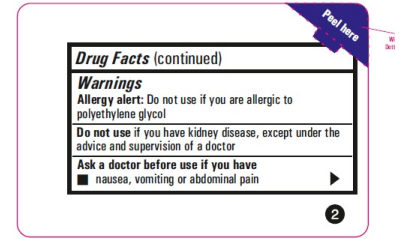
Top Layer



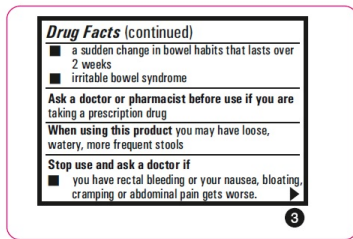
Top Layer Back



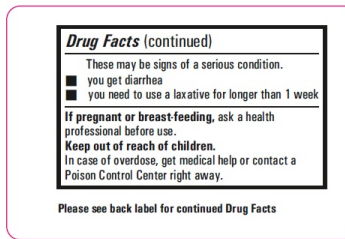
Second Layer



Second Layer Back

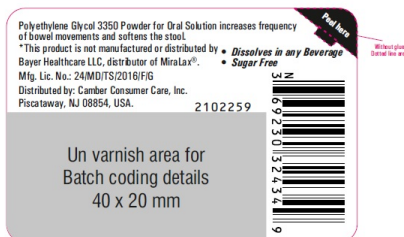


Third Layer

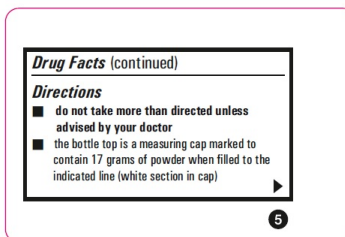


## Back Labels

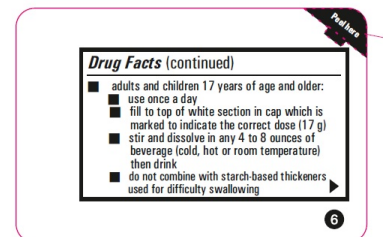
Top Layer



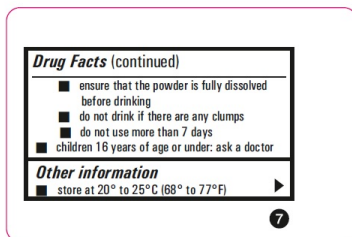
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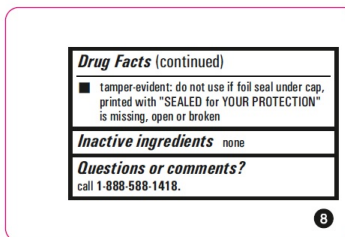
Second Layer



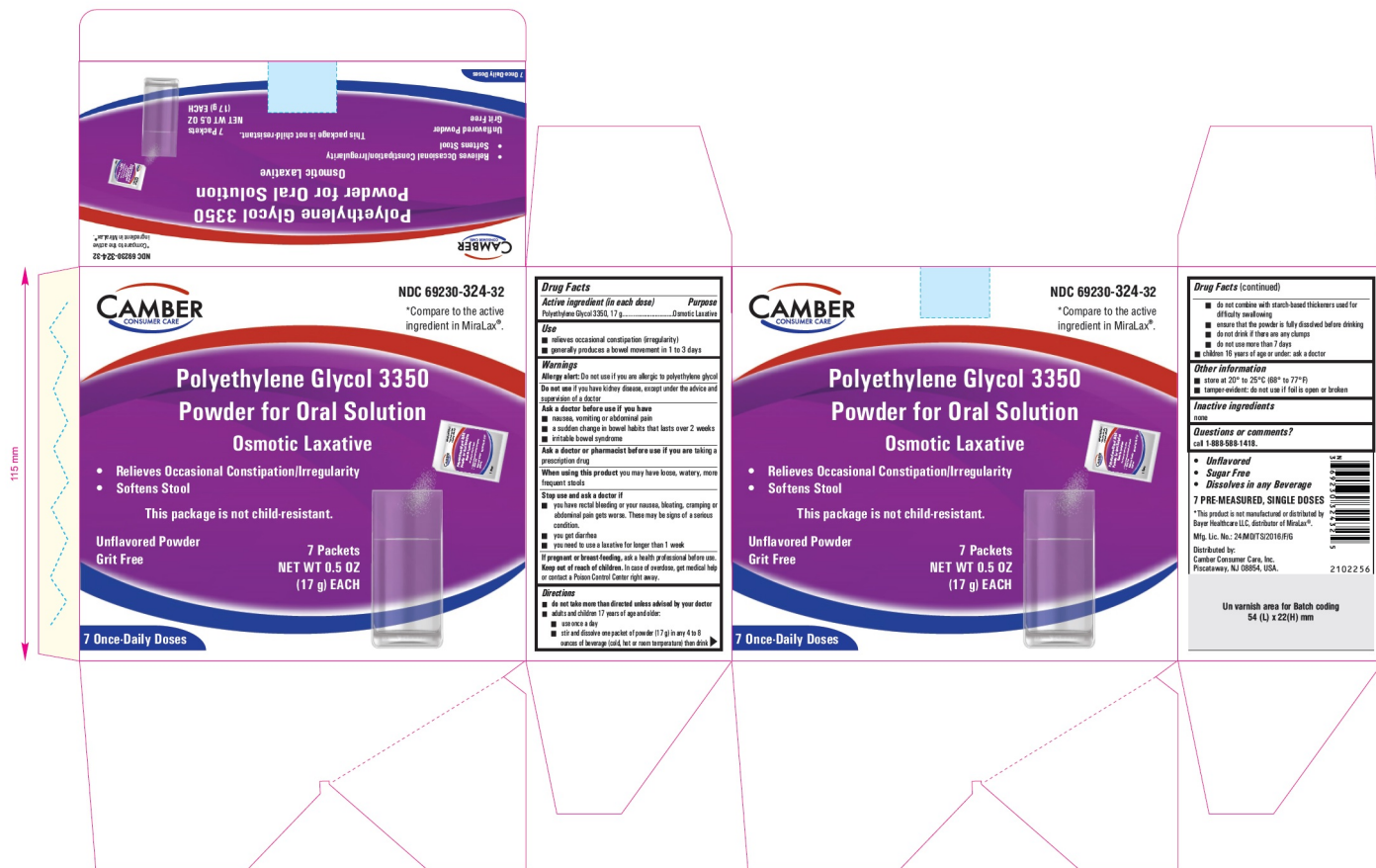
Second Layer Back



Third Layer



Polyethylene glycol 3350 powder for oral solution carton label



## POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

### Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:69230-324
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
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<b>1</b>	NDC:69230-324-32	7 in 1 CARTON	04/14/2021	
<b>1</b>		17 g in 1 PACKET; Type 0: Not a Combination Product		
<b>2</b>	NDC:69230-324-33	10 in 1 CARTON	04/14/2021	
<b>2</b>		17 g in 1 PACKET; Type 0: Not a Combination Product		
<b>3</b>	NDC:69230-324-34	119 g in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2021	
<b>4</b>	NDC:69230-324-35	238 g in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2021	
<b>5</b>	NDC:69230-324-36	510 g in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2021	
<b>6</b>	NDC:69230-324-37	14 in 1 CARTON	04/14/2021	
<b>6</b>		17 g in 1 PACKET; Type 0: Not a Combination Product		
<b>7</b>	NDC:69230-324-38	100 in 1 CARTON	04/21/2025	
<b>7</b>		17 g in 1 PACKET; Type 0: Not a Combination Product		
<b>8</b>	NDC:69230-324-39	765 g in 1 BOTTLE; Type 0: Not a Combination Product	01/03/2025	
<b>9</b>	NDC:69230-324-40	40 in 1 CARTON	04/21/2025	
<b>9</b>		17 g in 1 PACKET; Type 0: Not a Combination Product		

## Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA214990	04/14/2021	

**Labeler** - Camber Consumer Care Inc (079539968)

## Establishment

Name	Address	ID/FEI	Business Operations
Annora Pharma Private Limited		650980746	manufacture(69230-324)

Revised: 4/2025

Camber Consumer Care Inc