

POLYETHYLENE GLYCOL 3350 - polyethylene glycol 3350 powder, for solution

Camber Consumer Care Inc

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

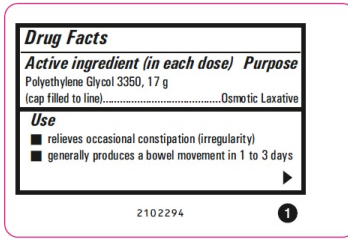
Polyethylene glycol 3350 powder for oral solution bottle label

Front Labels

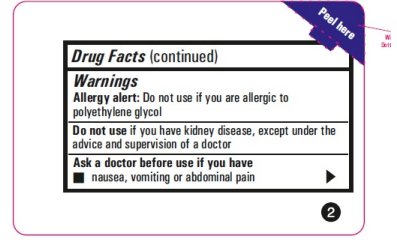
Top Layer



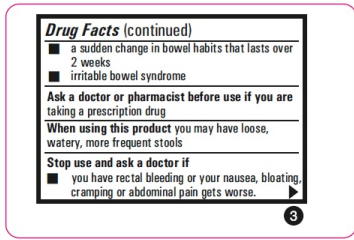
Top Layer Back



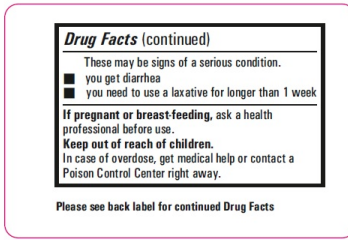
Second Layer



Second Layer Back



Third Layer

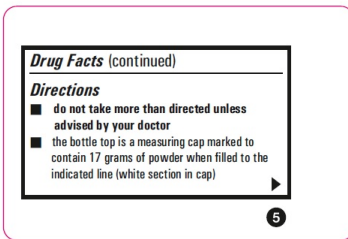


Back Labels

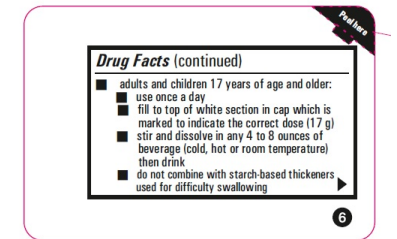
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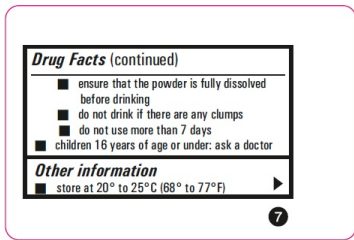
Top Layer Back



Second Layer



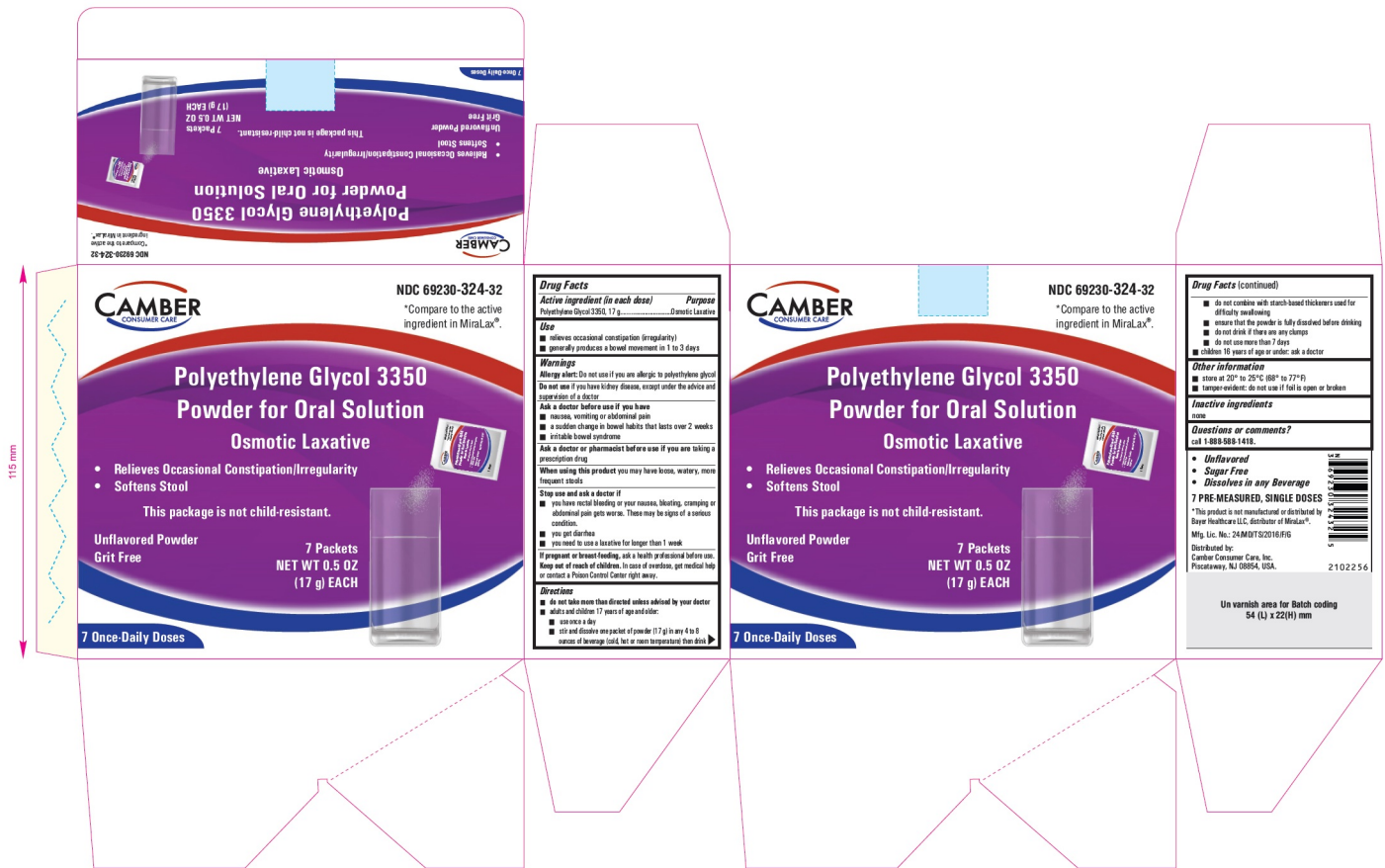
Second Layer Back



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

1	NDC:69230-324-32	7 in 1 CARTON	04/14/2021	
1		17 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:69230-324-33	10 in 1 CARTON	04/14/2021	
2		17 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:69230-324-34	119 g in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2021	
4	NDC:69230-324-35	238 g in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2021	
5	NDC:69230-324-36	510 g in 1 BOTTLE; Type 0: Not a Combination Product	04/14/2021	
6	NDC:69230-324-37	14 in 1 CARTON	04/14/2021	
6		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: 3/2023

Camber Consumer Care Inc