

POLYETHYLENE GLYCOL 3350- polyethylene glycol 3350 powder, for solution
ANI Pharmaceuticals, Inc.

Polyethylene Glycol 3350

Active Ingredient (in each dose)

Polyethylene Glycol 3350 USP, 17g

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**
- 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 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° to 25°C (68° to 77°F)
- tamper-evident: do not use if printed foil pouch is open or broken

Inactive ingredients

None

Questions or comments?

1-800-308-6755

Distributed by:

**ANI Pharmaceuticals, Inc.
Baudette, MN 56623**

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PRINCIPAL DISPLAY PANEL

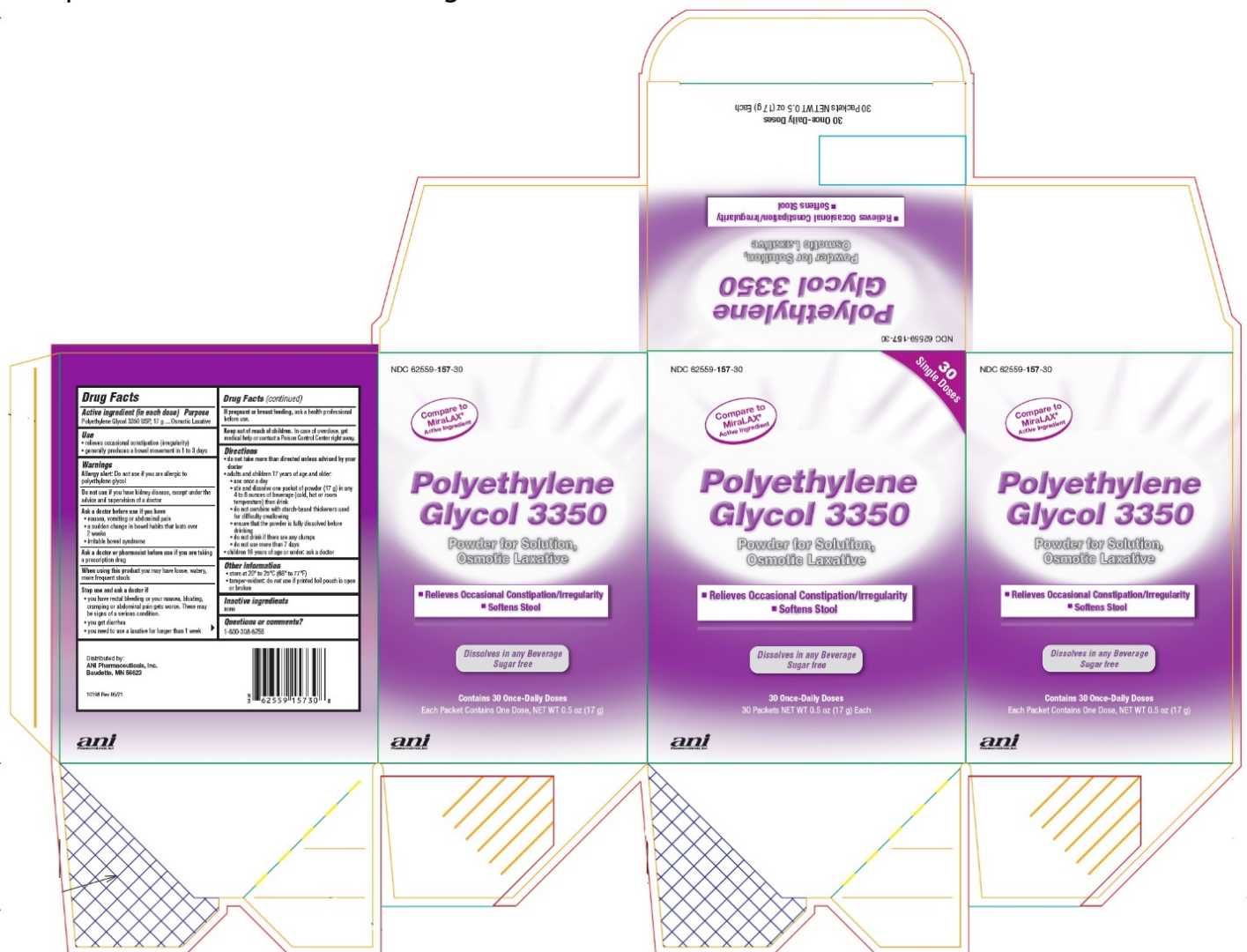
NDC 62559-157-30 Polyethylene Glycol 3350 Powder for Solution, Osmotic Laxative

- Relieves Occasional Constipation/Irregularity
- Softens Stool

Dissolves in any Beverage
Sugar free

30 Once-Daily Doses
30 Packets NET WT 0.5 oz (17 g) Each
30 Single Doses

Compare to MiraLAX® Active Ingredient



POLYETHYLENE GLYCOL 3350
polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:62559-157
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:62559-157-30	30 in 1 CARTON	03/24/2020	
1	NDC:62559-157-17	17 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:62559-157-10	100 in 1 CARTON	03/24/2020	
2	NDC:62559-157-17	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	ANDA202850	03/24/2020	

Labeler - ANI Pharmaceuticals, Inc. (145588013)

Revised: 5/2021

ANI Pharmaceuticals, Inc.