

**POLYETHYLENE GLYCOL 3350- polyethylene glycol 3350 powder, for solution**  
**Kesin Pharma Corporation**

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**Polyethelene Glycol 3350 Powder for OralSolution**

**Polyethylene Glycol 3350 increases frequency of bowel movements and softens stools**

***Drug Facts***

***Active ingredient (in each dose)***

Polyethlene 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 need to use a laxative for longer than 1 week
- you get diarrhea

**If pregnant or breast-feeding,**

ask a health professional before use.

**Keep out of the 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 ounce 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°C to 25°C (68°F to 77°F)
- **tamper-evident: do not use if printed foil pouch is open or broken**
- **this package is not child-resistant**

***Inactive ingredients***

none

***Questions or comments?***

Call 1-833-537-4679

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**TAMPER-EVIDENT: DO NOT USE IF FOIL IS OPEN OR BROKEN**

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\*This product is not manufactured by Bay HealthCare LLC, owner of the registered trademark MiraLAX<sup>®</sup>

Distributed by:

**Kesin Pharma**

Oldsmar, FL 34677



## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

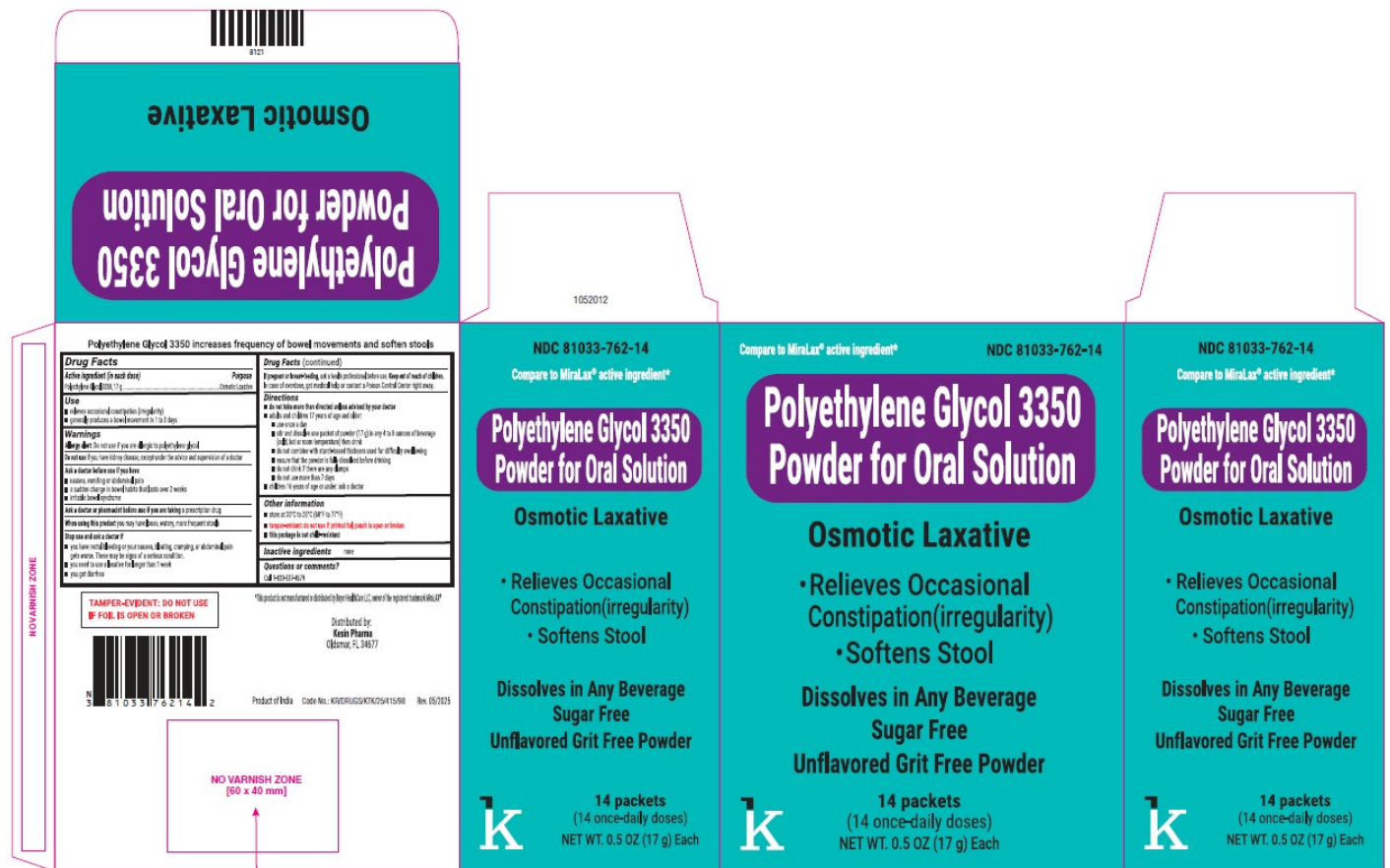
NDC 81033-762-14

Polyethylene Glycol 3350 Powder for Oral Solution

Osmotic Laxative

14 Packets

(14 once-daily-doses)



## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

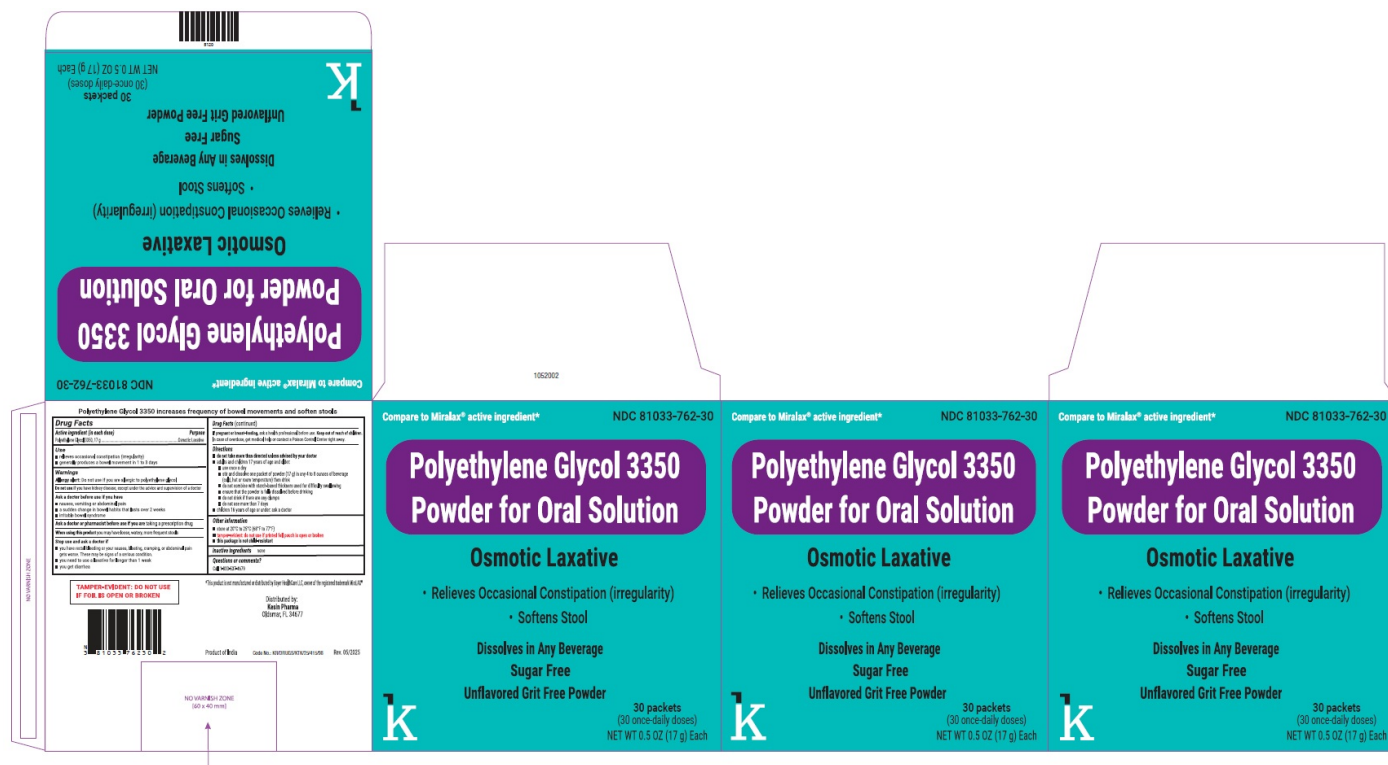
NDC 81033-762-30

Polyethylene Glycol 3350 Powder for Oral Solution

Osmotic Laxative

30 Packets

(30 once-daily doses)



## PACKAGE LABEL.PRINCIPAL DISPLAY PANEL

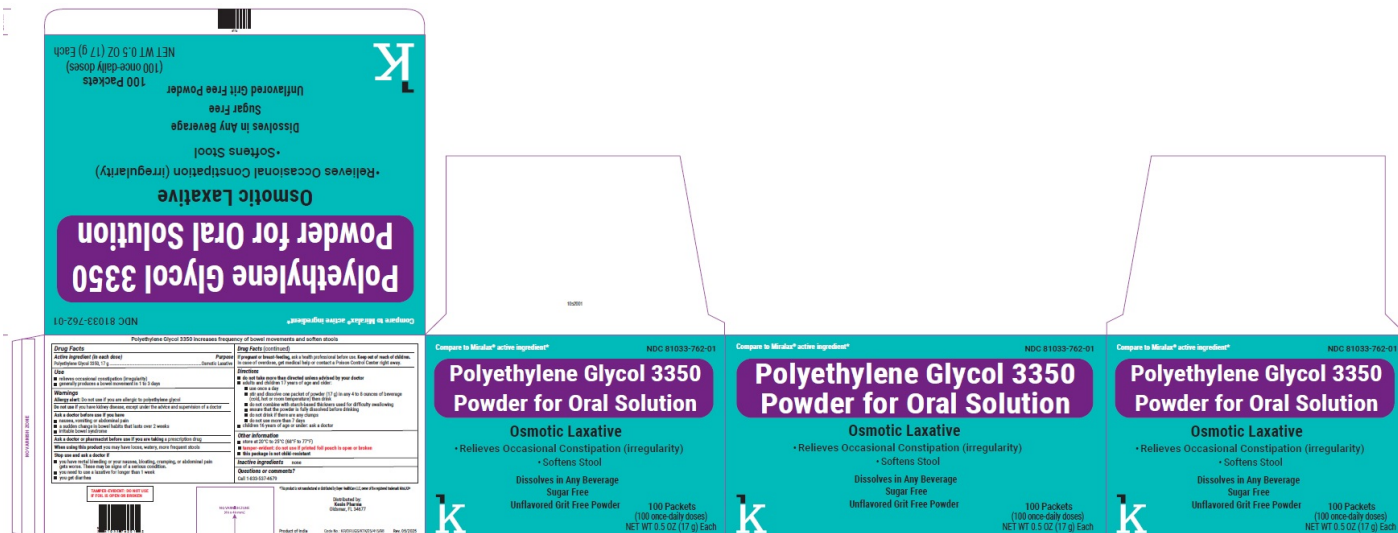
NDC 81033-762-01

Polyethylene Glycol 3350 Powder for Oral Solution

Osmotic laxative

100 Packets

(100 once-daily doses)



# POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

Product Information				
Product Type		HUMAN OTC DRUG	Item Code (Source)	NDC:81033-762(NDC:59556-762)
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 (Colorless upon dissolution)		Score	
Shape			Size	
Flavor			Imprint Code	
Contains				
Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:81033-762-14	14 in 1 CARTON	06/09/2025	
1	NDC:81033-762-17	17 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:81033-762-30	30 in 1 CARTON	06/09/2025	
2	NDC:81033-762-17	17 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:81033-762-01	100 in 1 CARTON	06/09/2025	
3	NDC:81033-762-17	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	ANDA203928		06/09/2025	

**Labeler** - Kesin Pharma Corporation (117447816)

## Establishment

Name	Address	ID/FEI	Business Operations
Kesin Pharma Corporation		117447816	label(81033-762) , pack(81033-762) , repack(81033-762)