

**POLYETHYLENE GLYCOL 3350- polyethylene glycol 3350 powder, for solution**  
**SKY Packaging**

-----  
**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?***

1-888-243-4363

Packaged by:  
Novitium Pharma LLC  
East Windsor, NJ 08520

Distributed by:  
McKesson Corporation dba SKY Packaging  
Memphis, TN 38141

Issued: 05/2024

LB4717-00

# PRINCIPAL DISPLAY PANEL

## NDC 63739-760-03 Polyethylene Glycol 3350 Powder for Solution, Osmotic Laxative

- Relieves Occasional Constipation/Irregularity
- Softens Stool

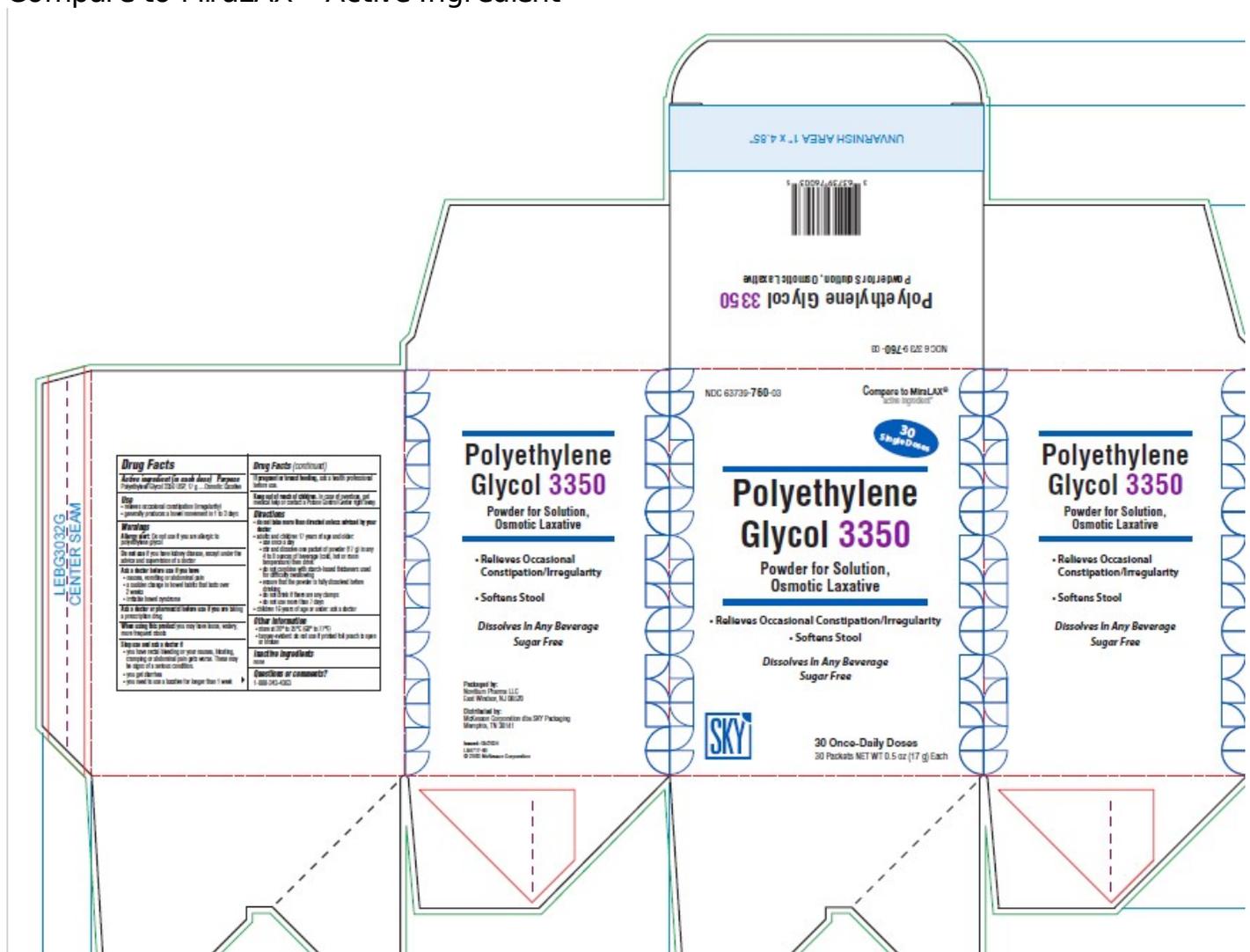
Dissolves in any Beverage  
Sugar free

### 30 Once-Daily Doses

30 Packets NET WT 0.5 oz (17 g) Each

30 Single Doses

Compare to MiraLAX<sup>®</sup> Active Ingredient



## POLYETHYLENE GLYCOL 3350

polyethylene glycol 3350 powder, for solution

### Product Information

<b>Product Type</b>	HUMAN OTC DRUG	<b>Item Code (Source)</b>	NDC:63739-760
<b>Route of Administration</b>	ORAL		

**Active Ingredient/Active Moiety**

Ingredient Name	Basis of Strength	Strength
<b>POLYETHYLENE GLYCOL 3350</b> (UNII: G2M7P15E5P) (POLYETHYLENE GLYCOL 3350 - UNII:G2M7P15E5P)	POLYETHYLENE GLYCOL 3350	17 g in 17 g

**Product Characteristics**

<b>Color</b>	white	<b>Score</b>	
<b>Shape</b>		<b>Size</b>	
<b>Flavor</b>		<b>Imprint Code</b>	
<b>Contains</b>			

**Packaging**

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:63739-760-03	30 in 1 CARTON	08/01/2024	08/02/2024
1	NDC:63739-760-01	17 g in 1 PACKET; Type 0: Not a Combination Product		
2	NDC:63739-760-04	100 in 1 CARTON	08/01/2024	09/30/2026
2	NDC:63739-760-01	17 g in 1 PACKET; Type 0: Not a Combination Product		
3	NDC:63739-760-02	14 in 1 CARTON	08/01/2024	06/30/2026
3	NDC:63739-760-01	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	08/01/2024	09/30/2026

**Labeler** - SKY Packaging (140529962)