POLYETHYLENE GLYCOL 3350 NF- polyethylene glycol 3350 powder, for solution
SUNRISE PHARMACEUTICAL, INC

Polyethylene Glycol 3350 powder, for solution

Drug Facts

Active ingredient (in each dose)

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

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 doctor or pharmacist before use if you are

taking a prescription drug

When using this product

you may 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**
- the bottle top is a measuring cap marked to contain 17 grams of powder when filled to the indicated line (clear section in cap)
- adults and children 17 years of age and older:
  - fill to top of clear 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
  - use once a day
  - use no more than 7 days
- children 16 years of age or under: ask a doctor

Other information

- store at 20° - 25°C (68° - 77°F)
- tamper- evident: do not use if foil seal under cap, printed with “SEALED for YOUR PROTECTION” is missing, open or broken

Inactive ingredient

none

Questions or comments?

1-800-FDA-1088

Manufactured & Distributed by:
Sunrise Pharmaceutical, Inc.
Rahway, NJ 07065

PRINCIPAL DISPLAY PANEL

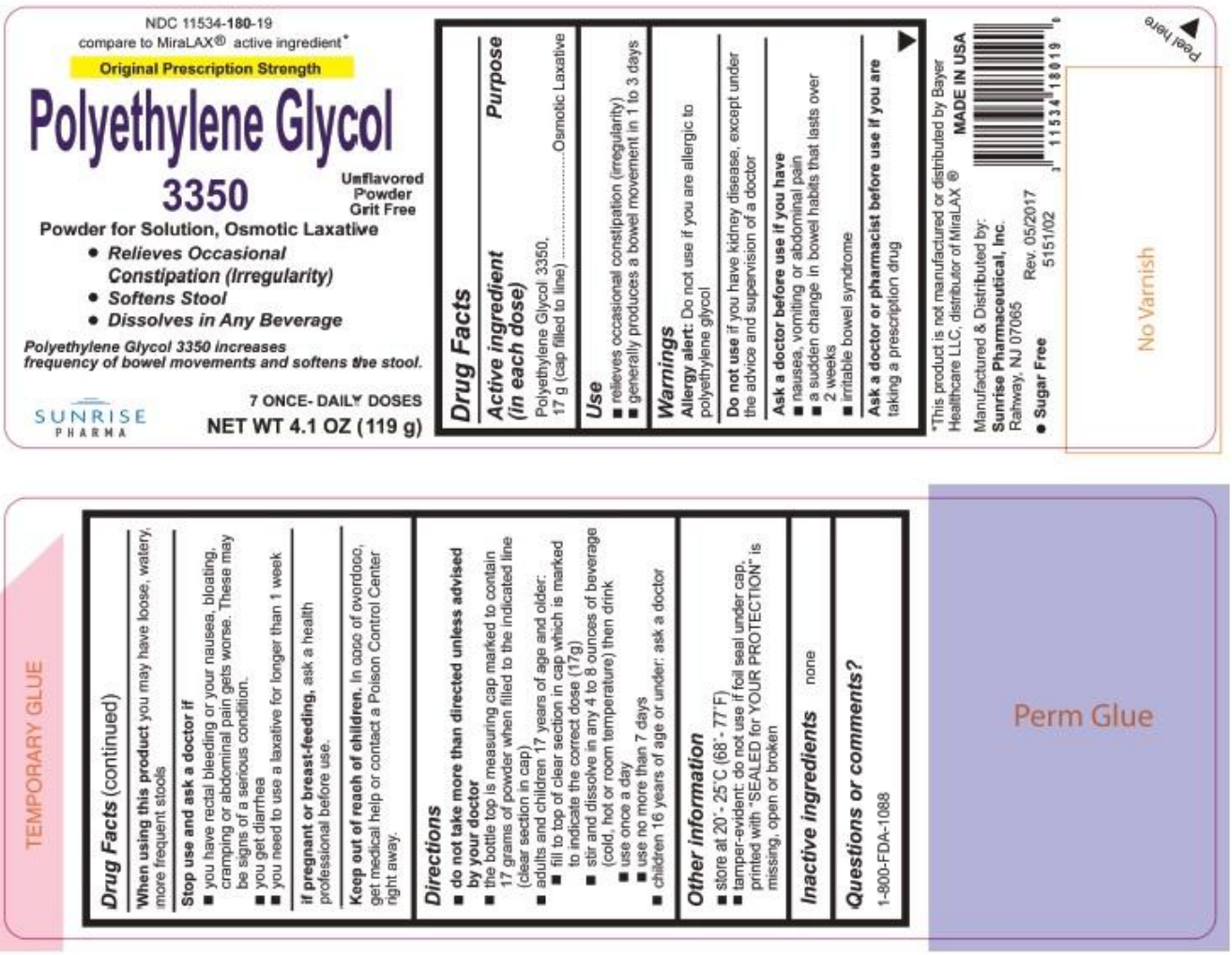
NDC 11534-**180**-19

Polyethylene Glycol

3350

Powder for Solution, Osmotic Laxative

- **Relieves Occasional Constipation/Irregularity**
- **Softens Stool**
- **Dissolves in Any Beverage**
  Unflavored Powder Grit Free
  Polyethylene Glycol 3350 increases frequency of bowel movements and softens the stool.

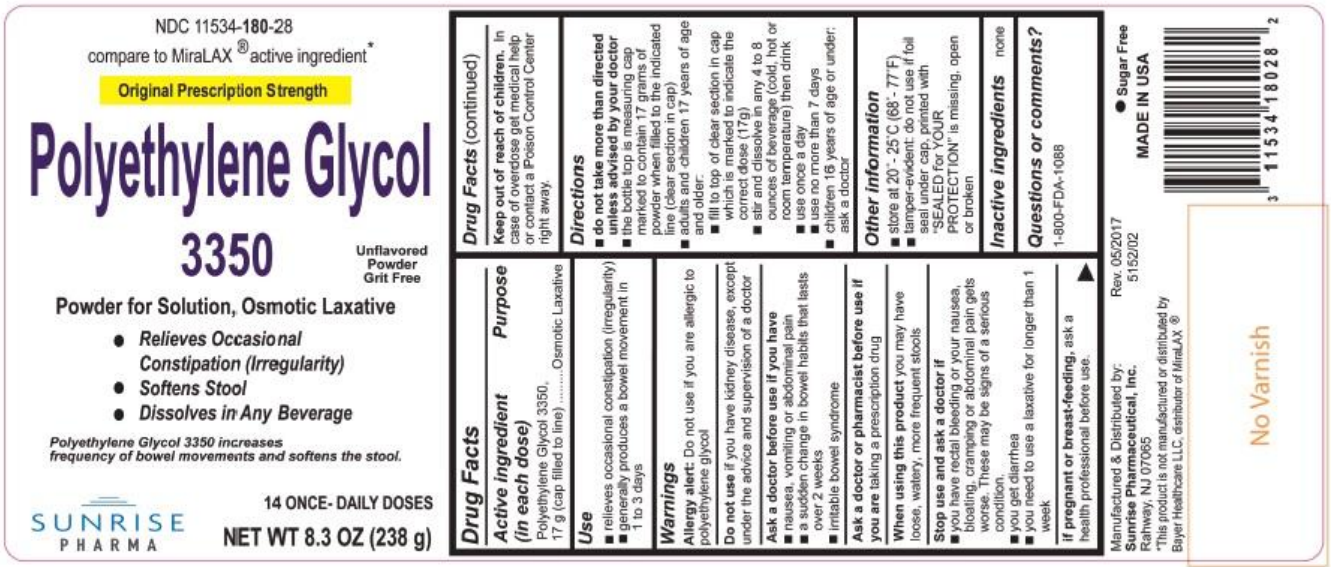


NDC 11534-**180**-28
Polyethylene Glycol
3350
Powder for Solution, Osmotic Laxative

- **Relieves Occasional Constipation/Irregularity**
- **Softens Stool**
- **Dissolves in Any Beverage**

Unflavored Powder Grit Free

Polyethylene Glycol 3350 increases frequency of bowel movements and softens the stool.

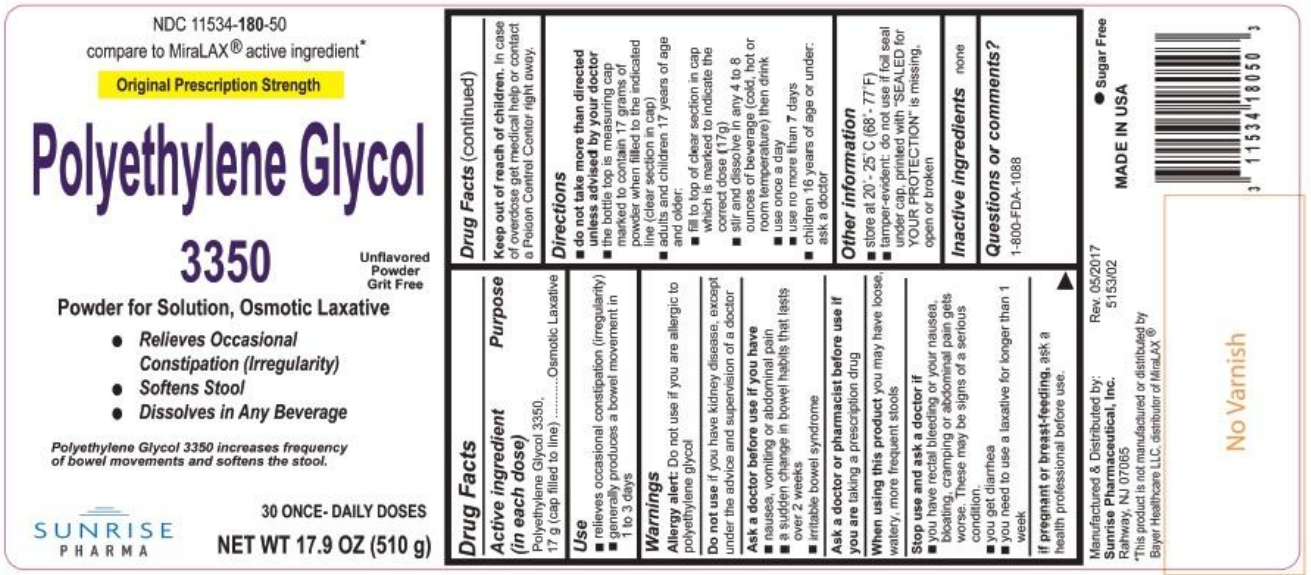


NDC 11534-**180**-50
Polyethylene Glycol
3350
Powder for Solution, Osmotic Laxative

- **Relieves Occasional Constipation/Irregularity**
- **Softens Stool**
- **Dissolves in Any Beverage**

Unflavored Powder Grit Free

Polyethylene Glycol 3350 increases frequency of bowel movements and softens the stool.



POLYETHYLENE GLYCOL 3350 NF

polyethylene glycol 3350 powder, for solution

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:11534-180

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:11534-180-19	119 g in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2017	
2	NDC:11534-180-28	238 g in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2017	
3	NDC:11534-180-50	510 g in 1 BOTTLE; Type 0: Not a Combination Product	06/13/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206105	06/13/2017	

Labeler - SUNRISE PHARMACEUTICAL, INC (168522378)

Registrant - SUNRISE PHARMACEUTICAL, INC (168522378)

Establishment

Name	Address	ID/FEI	Business Operations
SUNRISE PHARMACEUTICAL INC.		168522378	MANUFACTURE(11534-180) , ANALYSIS(11534-180) , PACK(11534-180)

Revised: 1/2020 SUNRISE PHARMACEUTICAL, INC