# **POLYETHYLENE GLYCOL 3350 NF - polyethylene glycol 3350 powder, for solution NUVO 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

#### Uses

- 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

Distributed by: Nuvo Pharmaceutical, Inc. Rahway, NJ 07065

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

# PRINCIPAL DISPLAY PANEL-119 g per Bottle

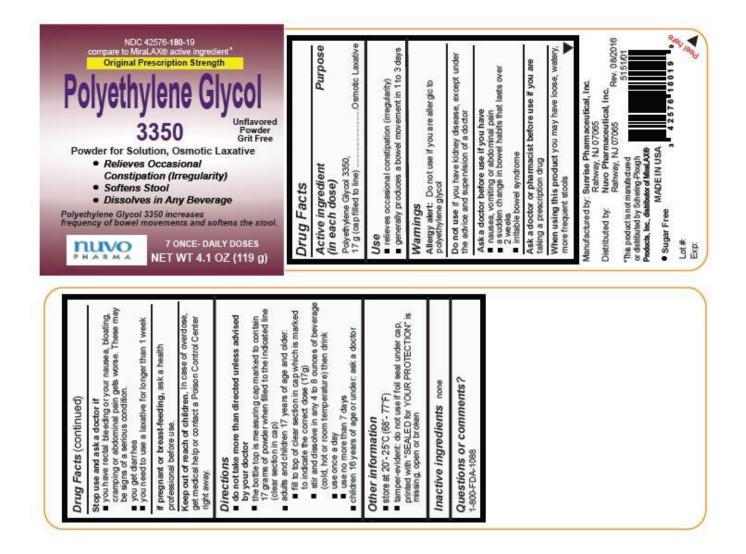
NDC 425756-**180**-19

Polyethylene Glycol

3350

Powder for Solution, Osmotic Laxative

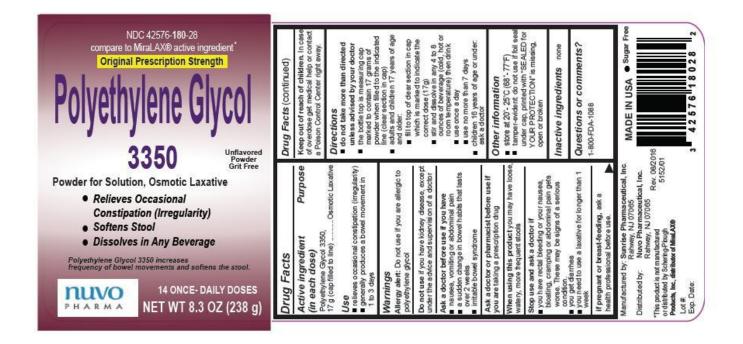
- Relieves Occasional Constipation/Irregularity
- Softens Stool
- Dissolves in Any Beverage Unflavored Powder Grit Free Polyethylene Glycol 3350 increases frequency of bowel movements and softens the stool.



#### PRINCIPAL DISPLAY PANEL -238 g per Bottle

NDC 425756**-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.



# PRINCIPAL DISPLAY PANEL -510 g per Bottle

NDC 425756-**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.

NDC 42576-180-50 compare to MiraLAX® active ingredient* Original Prescription Strength POLYECTION Strength 3350 Untravored Brit Free	<ul> <li>Drug Facts (continued)</li> <li>If pregrant or breast-feeding, ask a health professional before use.</li> <li>A health professional before use.</li> <li>of exercises get medical help or contact a Poisson Control Center right away.</li> <li>a Poisson Control Center right away.</li> <li>a not ast as advised by your doctor unless advised by your doctor andred to not allow and color the bottle top is measuring cap provide when illed to the indicated marked to come of age and older.</li> <li>a the bottle top is measuring cap addits and children 17 years of age which is marked to indicate the come of age which is marked to indicate the control does (170)</li> <li>a tand dissolve in any 4 to 8 or nom temperature) then drink.</li> <li>a tea once a day.</li> <li>use on more aday.</li> <li>use on more aday.</li> <li>use on more aday.</li> <li>the on more than 7 days for ournos of age or under so the right and choic row of age or tow of age or tow of age or ournos of age or now then the addition of the same of the right and addition for the same of the ournes of age or now the presture) then drink.</li> </ul>	00-FDA-1088
Grit Free Powder for Solution, Osmotic Laxative • Relieves Occasional Constipation (Irregularity) • Softens Stool • Dissolves in Any Beverage Polyethylene Glycol 3350 increases frequency of bowel movements and softens the stool. 30 ONCE- DAILY DOSES NET WT 17.9 OZ (510 g)	Drug Facts       Active ingredient     Purpose       fine acch dose)     Purpose       fine acch dose)     Purpose       Parently produces a bowel movement in 17 g (rep fillectoline)Cemotic Lawative generality produces a bowel movement in 17 g (rep fillectoline)     Purpose       Warnings     Marchings     Purpose       Marnings     Marnings     Powel Purpose       Marnings     Powel Purpose     Powel Purpose       Marnings     Powel Purpose     Powel Purpose       Marnings     Powel Purpose     Powel Purpose       Allegy ahert: Do not use if you are allergic to polyethylene gycol     Powel Purpose       Marnings     Audeor the advoce and supervision of a doctor     Powel Purpose       Pak a doctor before use if you have a cudden change in bowel Publics that lasts     Powel 2 weeks       Initiable bowel syndrome     Ask a doctor or pharmacist before use if you are taking a presendent of rog       Men using this product you may have loose, wore: Twee and set a doctor if     Pou wave loose, wore: Twee and be a doctor if       Stop use and ask a doctor of a sectors wore: Where using a resolution of a sectors     Pou have ectal breading or sectors       Stop use and ask a doctor of a sectors     Pou have ectal breading or sectors       Stop use and ask a doctor of a sectors     Pou have ectal breading or sectors       Stop use and ask a doctor of a sectors     Pou have ectal breading or sect	week I all

polyethylene glycol 3350 powder, for solution									
Product Information									
Product Type			HUMAN OTC DRUG Item C		tem Coo	ode (Source)		NDC:42576-180	
Route of Administration			ORAL						
Active Ingredient/Active Moiety									
	Ingredient Name				Basis of S			Strength	Strength
	POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P) (POLYETUNII:G2M7P15E5P)			THYLENE				ENE GLYCOL	17 g in 17 g
Р	roduct Characte	eristics							
Color			WHITE	Score					
Shape				Size					
Flavor			Imprint Code						
Contains									
Packaging									
#	Item Code		Package Description			Marketing Start Date		Marketing End Date	
1	NDC:42576-180-19	119 g in 1 BOT	LE; Type 0: Not a Combination Product		duct (	07/03/2017			
	NDC:42576-180-28	0	TLE; Type 0: Not a Combination Product			07/03/2017			
3	NDC:42576-180-50	510 g in 1 BOTTLE; Type 0: Not a Combination Product 07/03/2017							
Marketing Information									
Marketing Category Application Number or Mono			on Number or Monogra	nh Citati	ion	Marketing	g Start Date	Marketing	End Date
		ANDA20610				07/03/2017		inur ac ung	Life Dutt
_									

Labeler - NUVO PHARMACEUTICAL INC. (078366708)

Registrant - NUVO PHARMACEUTICAL INC. (078366708)

# Establishment

Name	Address	ID/FEI	Business Operations
SUNRISE PHARMACEUTICAL INC.		168522378	MANUFACTURE(42576-180), ANALYSIS(42576-180), PACK(42576-180)

Revised: 1/2017

NUVO PHARMACEUTICAL INC.