

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.**

NDC 42576-180-19
compare to MiraLAX® active ingredient*
Original Prescription Strength

Polyethylene Glycol


3350

Unflavored Powder 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.



7 ONCE- DAILY DOSES
NET WT 4.1 OZ (119 g)

Drug Facts

Active ingredient (in each dose)
Polyethylene Glycol 3350, 17 g (cap filled to line) 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

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

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

Rev. 06/2016
515101



MADE IN USA

● Sugar Free

Lot #:
Exp:

Peel here

Drug Facts (continued)

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 measuring cap marked to contain 17 grams of powder when filled to the indicated line (clear section in cap)
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 - 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 ingredients none

Questions or comments?
1-800-FDA-1088

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.

NDC 42576-180-28
compare to MiraLAX® active ingredient*
Original Prescription Strength

Polyethylene Glycol 3350


Unflavored Powder 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.

nuvo PHARMA 14 ONCE- DAILY DOSES
NET WT 8.3 OZ (238 g)

<p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> do not take more than directed unless advised by your doctor the bottle top is 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: <ul style="list-style-type: none"> fill to top of clear section in cap which is marked to indicate the correct dose (17g) 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 	<p>Drug Facts</p> <p>Active ingredient (in each dose) Polyethylene Glycol 3350, 17 g (cap filled to line).....Osmotic Laxative</p> <p>Use</p> <ul style="list-style-type: none"> relieves occasional constipation (irregularity) generally produces a bowel movement in 1 to 3 days <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to polyethylene glycol</p> <p>Do not use if you have kidney disease, except under the advice and supervision of a doctor</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> nausea, vomiting or abdominal pain a sudden change in bowel habits that lasts over 2 weeks irritable bowel syndrome <p>Ask a doctor or pharmacist before use if you are taking a prescription drug</p> <p>When using this product you may have loose, watery, more frequent stools</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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. <p>If pregnant or breast-feeding, ask a health professional before use.</p>
<p>Other information</p> <ul style="list-style-type: none"> 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 <p>Inactive ingredients none</p> <p>Questions or comments? 1-800-FDA-1088</p>	<p>MADE IN USA ● Sugar Free</p>  <p>3 42576 18028 12</p> <p>Manufactured by: Sunrise Pharmaceutical, Inc. Rahway, NJ 07065</p> <p>Distributed by: Nuvo Pharmaceutical, Inc. Rahway, NJ 07065</p> <p>*This product is not manufactured or distributed by Schering-Plough Products, Inc., distributor of MiraLAX®</p> <p>Lot #: 082016 5152/01</p> <p>Exp. Date:</p>

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

Polyethylene Glycol 3350


Unflavored Powder 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.

nuvo PHARMA 30 ONCE- DAILY DOSES
NET WT 17.9 OZ (510 g)

<p>Drug Facts (continued)</p> <p>Keep out of reach of children. In case of overdose get medical help or contact a Poison Control Center right away.</p> <p>Directions</p> <ul style="list-style-type: none"> do not take more than directed unless advised by your doctor the bottle top is 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: <ul style="list-style-type: none"> fill to top of clear section in cap which is marked to indicate the correct dose (17g) 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 	<p>Drug Facts</p> <p>Active ingredient (in each dose) Polyethylene Glycol 3350, 17 g (cap filled to line).....Osmotic Laxative</p> <p>Use</p> <ul style="list-style-type: none"> relieves occasional constipation (irregularity) generally produces a bowel movement in 1 to 3 days <p>Warnings</p> <p>Allergy alert: Do not use if you are allergic to polyethylene glycol</p> <p>Do not use if you have kidney disease, except under the advice and supervision of a doctor</p> <p>Ask a doctor before use if you have</p> <ul style="list-style-type: none"> nausea, vomiting or abdominal pain a sudden change in bowel habits that lasts over 2 weeks irritable bowel syndrome <p>Ask a doctor or pharmacist before use if you are taking a prescription drug</p> <p>When using this product you may have loose, watery, more frequent stools</p> <p>Stop use and ask a doctor if</p> <ul style="list-style-type: none"> 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. <p>If pregnant or breast-feeding, ask a health professional before use.</p>
<p>Other information</p> <ul style="list-style-type: none"> 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 <p>Inactive ingredients none</p> <p>Questions or comments? 1-800-FDA-1088</p>	<p>MADE IN USA ● Sugar Free</p>  <p>3 42576 18050 3</p> <p>Manufactured by: Sunrise Pharmaceutical, Inc. Rahway, NJ 07065</p> <p>Distributed by: Nuvo Pharmaceutical, Inc. Rahway, NJ 07065</p> <p>*This product is not manufactured or distributed by Schering-Plough Products, Inc., distributor of MiraLAX®</p> <p>Lot #: 082016 5153/01</p> <p>Exp. Date:</p>

polyethylene glycol 3350 powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:42576-180
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:42576-180-19	119 g in 1 BOTTLE; Type 0: Not a Combination Product	07/03/2017	
2	NDC:42576-180-28	238 g in 1 BOTTLE; 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 Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA206105	07/03/2017	

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.