

POLYETHYLENE GLYCOL 3350, NF POWDER FOR SOLUTION, LAXATIVE- polyethylene glycol 3350, nf powder for solution, laxative powder, for solution
Nexgen Pharma, Inc.

Drug Facts

Active ingredient (in each dose)

Polyethylene Glycol 3350, 17 grams (cap filled to the top)

Purpose

Osmotic Laxative

Keep Out of Reach of Children

In case of overdose, get medical help or contact a Poison Control Center right away.

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 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.

Directions

- **Do not take more than directed unless advised by your doctor.**

- The bottle cap is a measuring cup designed to contain 17 grams of powder when filled to the top rim.
- Adults and children 17 years of age and older:
 - Fill to the top of the bottle cap which will provide the correct dose (17 g).
 - Stir and dissolve in any 4 to 8 ounces of beverage (cold, hot, or room temperature), then drink.
 - Ensure that the powder is fully dissolved before drinking.
 - Do not drink if there are any clumps.
 - Use once a day.
 - Use no more than 7 days.

Children 16 years of age or younger, ask a doctor.

Other Information

- Store at 20°C – 25°C (68°F – 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?

For serious adverse events call Nexgen Pharma, Inc. at 1-888-710-0006 or contact online at www.nexgenpharma.com.

Manufactured by: Nexgen Pharma, Inc., Irvine, CA 92606, USA

Rev. 09/2019

Label Principal Display Panel

17.9 oz Container Label

Dissolves in Any Beverage

NDC 0722-7116-03

Nexgen Polyethylene Glycol 3350, NF
increases the frequency of bowel
movements and softens the stool

Original
Prescription
Strength

NEXGEN Polyethylene Glycol 3350, NF Powder for Solution, Laxative

- Relieves Occasional Constipation
- Softens Stool

Net Wt. 17.9 OZ (510 g)
30 ONCE-DAILY DOSES

Drug Facts (continued)

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 cap is a measuring cup designed to contain 17 grams of powder when filled to the top rim
- adults and children 17 years of age and older
 - fill to the top of the bottle cap which will provide 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 younger: 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?
1-888-710-0006 or www.nexgenpharma.com

Manufactured by:
Nexgen Pharma, Inc.
Irvine, California 92614 Rev. 07/09

Drug Facts

Active Ingredient (in each dose)	Purpose
Polyethylene Glycol 3350, 17g (cap filled to the top)	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



Label Principal Display Panel

9 oz Container Label

Dissolves in Any Beverage

NDC 0722-7116-02

Nexgen Polyethylene Glycol 3350, NF
increases the frequency of bowel
movements and softens the stool

Original
Prescription
Strength

NEXGEN Polyethylene Glycol 3350, NF Powder for Solution, Laxative

- Relieves Occasional Constipation
- Softens Stool

Net Wt. 9 OZ (238 g)
14 ONCE-DAILY DOSES

Drug Facts (continued)

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 cap is a measuring cup designed to contain 17 grams of powder when filled to the top rim
- adults and children 17 years of age and older
 - fill to the top of the bottle cap which will provide 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 younger: 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?
1-888-710-0006 or www.nexgenpharma.com

Manufactured by:
Nexgen Pharma, Inc.
Irvine, California 92614 Rev. 07/09

Drug Facts

Active Ingredient (in each dose)	Purpose
Polyethylene Glycol 3350, 17g (cap filled to the top)	Laxative

Use

- relieves occasional constipation (irregularity)
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Warnings

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- 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



Label Principal Display Panel

4.1 oz Container Label - Drug Facts on Extended Content Label

*Dissolves in
Any Beverage*

NDC 0722-7116-01

**Original
Prescription
Strength**

NEXGEN
Polyethylene Glycol 3350, NF
Powder for Solution, Laxative

- Relieves Occasional Constipation
- Softens Stool

Net Wt. 4.1 OZ (119 g)

7 ONCE-DAILY DOSES

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Rev. 07/09



POLYETHYLENE GLYCOL 3350, NF POWDER FOR SOLUTION, LAXATIVE

polyethylene glycol 3350, nf powder for solution, laxative powder, for solution

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0722-7116
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 1 d

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:0722-7116-01	7 d in 1 BOTTLE; Type 0: Not a Combination Product	10/07/2009	
2	NDC:0722-7116-02	14 d in 1 BOTTLE; Type 0: Not a Combination Product	10/07/2009	
3	NDC:0722-7116-03	30 d in 1 BOTTLE; Type 0: Not a Combination Product	10/07/2009	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090812	10/07/2009	

Labeler - Nexgen Pharma, Inc. (048488621)

Registrant - Nexgen Pharma, Inc. (048488621)

Establishment

Name	Address	ID/FEI	Business Operations
Nexgen Pharma, Inc.		160356114	ANALYSIS(0722-7116) , LABEL(0722-7116) , MANUFACTURE(0722-7116) , PACK(0722-7116)

Revised: 9/2019

Nexgen Pharma, Inc.