

*Breckenridge Pharmaceutical, Inc.  
continues to market  
Polyethylene Glycol 3350 NF  
Powder for Oral Solution  
under the original  
ANDA's approved Rx version.*



**Still Available  
by Prescription**

See full prescribing  
information on back.

Prescription ("Rx") uses of Polyethylene Glycol 3350 Powder for Oral Solution ("PEG") remain approved and necessary. The FDA has concluded that Over-the Counter ("OTC") use of PEG is only appropriate for "no more than 7 days,"\* which is consistent with historic OTC drug use, and has approved an NDA for this OTC use. For laxative use of PEG longer than 7 days, a physician's intervention and prescription is required.

For different conditions of use or indications, the FDA does permit the same active ingredient with the same dosage but different labeling (i.e., dosing regimens) to exist as both Rx and OTC (e.g., Ranitidine HCl 150mg/ Zantac® 150mg).

Our Rx generic PEG is subject to an approved ANDA and has a unique, Rx-only dosing regimen (with FDA-mandated labeling) that is significantly different from the newly created OTC version. Our Rx version, approved under a separate ANDA, has been and remains medically appropriate. Therefore, our PEG product continues to be lawfully marketed.

For more information on our products,  
contact your wholesaler or distributor  
or visit us at [www.bpirx.com](http://www.bpirx.com).

\* Schering-Plough HealthCare Products MiraLAX® OTC labeling  
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**Breckenridge  
Pharmaceutical, Inc.**  
"Your ValuBrand™ Company"  
Boca Raton, FL 33487

# Polyethylene Glycol 3350 NF

## Polyethylene Glycol 3350 Powder for Oral Solution

### DESCRIPTION

A white powder for reconstitution. Polyethylene Glycol 3350 NF (polyethylene glycol 3350 powder for oral solution) is a synthetic polyglycol having an average molecular weight of 3350. The actual molecular weight is not less than 90.0 percent and not greater than 110.0 percent of the nominal value. The chemical formula is  $\text{HO}(\text{C}_2\text{H}_4\text{O})_n\text{H}$  in which  $n$  represents the average number of oxyethylene groups. Below 55°C it is a free flowing white powder freely soluble in water. Polyethylene Glycol 3350 NF is an osmotic agent for the treatment of constipation.

**Inactive Ingredient:** Butylated Hydroxytoluene

### CLINICAL PHARMACOLOGY

**Pharmacology:** Polyethylene Glycol 3350 NF is an osmotic agent which causes water to be retained with the stool. Essentially, complete recovery of Polyethylene Glycol 3350 NF was shown in normal subjects without constipation. Attempts at recovery of Polyethylene Glycol 3350 NF in constipated patients resulted in incomplete and highly variable recovery. In vitro study showed indirectly that Polyethylene Glycol 3350 NF was not fermented into hydrogen or methane by the colonic microflora in human feces. Polyethylene Glycol 3350 NF appears to have no effect on the active absorption or secretion of glucose or electrolytes. There is no evidence of tachyphylaxis.

### CLINICAL TRIALS

In one study, patients with less than 3 bowel movements per week were randomized to Polyethylene Glycol 3350 NF, 17 grams, or placebo for 14 days. An increase in bowel movement frequency was observed for both treatment groups during the first week of treatment. Polyethylene Glycol 3350 NF was statistically superior to placebo during the second week of treatment. In another study, patients with 3 bowel movements or less per week and/or less than 300 grams of stool per week were randomized to 2 dose levels of Polyethylene Glycol 3350 NF or placebo for 10 days each. Success was defined by an increase in both bowel movement frequency and daily stool weight. For both parameters, superiority of the 17 gram dose of Polyethylene Glycol 3350 NF over placebo was demonstrated.

### INDICATIONS AND USAGE

For the treatment of occasional constipation. This product should be used for 2 weeks or less as directed by a physician.

### CONTRAINDICATIONS

Polyethylene Glycol 3350 NF is contraindicated in patients with known or suspected bowel obstruction and patients known to be allergic to polyethylene glycol.

### WARNINGS

Patients with symptoms suggestive of bowel obstruction (nausea, vomiting, abdominal pain or distention) should be evaluated to rule out this condition before initiating Polyethylene Glycol 3350 NF therapy.

### PRECAUTIONS

**General:** Patients presenting with complaints of constipation should have a thorough medical history and physical examination to detect associated metabolic, endocrine and neurogenic conditions and medications. A diagnostic evaluation should include a structural examination of the colon. Patients should be educated about good defecatory and eating habits (such as high fiber diets) and lifestyle changes (adequate dietary fiber and fluid intake, regular exercise) which may produce more regular bowel habits.

Polyethylene Glycol 3350 NF should be administered after being dissolved in approximately 4 to 8 ounces of water, juice, soda, coffee or tea.

**Information for Patients:** Polyethylene Glycol 3350 NF softens the stool and increases the frequency of bowel movements by retaining water in the stool. It should always be taken by mouth after being dissolved in 4 to 8 ounces of water, juice, soda, coffee, or tea. Should unusual cramps, bloating, or diarrhea occur, consult your physician.

Two to 4 days may be required to produce a bowel movement. This product should be used for 2 weeks or less or as directed by your physician. Prolonged, frequent or excessive use of Polyethylene Glycol 3350 NF may result in electrolyte imbalance and dependence on laxatives.

**Laboratory Tests:** No clinically significant effects on laboratory tests have been demonstrated.

**Drug Interactions:** No specific drug interactions have been demonstrated.

**Carcinogenesis, Mutagenesis, Impairment of Fertility:** Long term carcinogenicity studies, genetic toxicity studies or reproductive toxicity studies in animals have not been performed with Polyethylene Glycol 3350 NF.

**Pregnancy: Category C.** Animal reproductive studies have not been performed with Polyethylene Glycol 3350 NF.

It is also not known whether Polyethylene Glycol 3350 NF can cause fetal harm when administered to a pregnant woman, or can affect reproductive capacity. Polyethylene Glycol 3350 NF should only be administered to a pregnant woman if clearly needed.

**Pediatric Use:** Safety and effectiveness in pediatric patients has not been established.

**Geriatric Use:** There is no evidence for special considerations when Polyethylene Glycol 3350 NF is administered to elderly patients.

In geriatric nursing home patients a higher incidence of diarrhea occurred at the recommended 17 g dose.

If diarrhea occurs Polyethylene Glycol 3350 NF should be discontinued.

### ADVERSE REACTIONS

Nausea, abdominal bloating, cramping and flatulence may occur. High doses may produce diarrhea and excessive stool frequency, particularly in elderly nursing home patients.

Patients taking other medications containing polyethylene glycol have occasionally developed urticaria suggestive of an allergic reaction.

### OVERDOSAGE

There have been no reports of accidental overdosage. In the event of overdosage, diarrhea would be the expected major event. If an overdose of drug occurred without

concomitant ingestion of fluid, dehydration due to diarrhea may result. Medication should be terminated and free water administered.

The oral LD<sub>50</sub> is >50 gm/kg in mice, rats and rabbits.

### DOSAGE AND ADMINISTRATION

The usual dose is 17 grams (about 1 heaping tablespoon) of powder per day (or as directed by physician) in 4 to 8 ounces of water, juice, soda, coffee, or tea. Each bottle of Polyethylene Glycol 3350 NF is supplied with a dosing cup marked to contain 17 grams of laxative powder when filled to the indicated line.

Two to 4 days (48 to 96 hours) may be required to produce a bowel movement.

### HOW SUPPLIED

In powdered form, for oral administration after dissolution in water, juice, soda, coffee, or tea. Polyethylene Glycol 3350 NF (Polyethylene Glycol 3350 Powder for Oral Solution) is available in two package sizes: a 500 cc container of 255 grams of laxative powder and a 950 cc container of 527 grams of laxative powder.

NDC 51991-457-58 Polyethylene Glycol 3350 NF 255g

NDC 51991-457-57 Polyethylene Glycol 3350 NF 527g

The dosing cup supplied with each bottle is marked with a measuring line and may be used to measure a single Polyethylene Glycol 3350 NF dose of 17 grams (about 1 heaping tablespoonful).

### Rx only

**Keep this and all medications out of the reach of children**

### STORAGE

Store at 20°–25°C (68°–77°F); excursions permitted to 15°–30°C (59°–86°F).

[See USP Controlled Room Temperature]

Distributed by: Breckenridge Pharmaceutical, Inc., Boca Raton, FL 33487

Manufactured by: Nexgen Pharma, Inc., Irvine, CA 92614

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### PATIENT INFORMATION

Polyethylene Glycol 3350 NF (Polyethylene Glycol 3350 Powder for Oral Solution) is a prescription only laxative which has been prescribed by your physician to treat constipation. This product should only be used by the person for whom it was prescribed.

#### How to take

The dose is 17 grams each day or as directed by physician. It should always be taken by mouth. Measure the dose using the dosing cup (or use one heaping tablespoon of powder), stir and dissolve in a glass (4 to 8 oz) of water, juice, soda, coffee, or tea. Taking more than the prescribed dose may cause loss of fluid due to severe diarrhea.

#### How will it work?

Polyethylene Glycol 3350 NF softens the stool and increases the frequency of bowel movements by retaining water in the stool. Your first bowel movement will usually happen in two to four days, although results may vary for individual patients.

#### How long should I take it?

Polyethylene Glycol 3350 NF achieves its best results when used between one and two weeks. You may discontinue taking the drug after you had several satisfactory bowel movements. Should unusual cramps, bloating, or diarrhea occur, consult your physician. Polyethylene Glycol 3350 NF is intended for up to a two week course of therapy. You should not use for a longer time unless directed by your physician.

#### Next Steps

After successfully completing Polyethylene Glycol 3350 NF therapy (usually between one and two weeks), please discuss with your physician lifestyle changes which may produce more regular bowel habits (adequate dietary and fluid intake, regular exercise).

#### Who should NOT take Polyethylene Glycol 3350 NF

Polyethylene Glycol 3350 NF should not be used by children. It should not be used by pregnant women unless prescribed by a physician.

#### Side Effects/Drug Reactions

Occasionally, Polyethylene Glycol 3350 NF may cause nausea, stomach fullness, cramping, diarrhea and/or gas. Do not take if you have symptoms such as nausea, vomiting, abdominal pain or distention, which may be due to bowel obstruction. On rare occasions hives and skin rashes have been reported which are suggestive of an allergic reaction. If you get an allergic reaction you should discontinue the medication and call your physician.

If you are allergic to polyethylene glycol, do not use this drug.

### Directions

#### Rx only

- Note: This product is supplied with a dosing cup marked to contain 17 grams of powder when filled to the indicated line.
- Daily dose is 17 grams per day or as directed by physician.
- Pour 17 grams (about 1 heaping tablespoon) of powder into the dosing cup.
- Stir the powder in a cup (4 to 8 oz) of water, juice, soda, coffee, or tea until completely dissolved.
- Drink the solution.
- Treatment for **2 to 4 days** may be required to produce a bowel movement.

**Keep this and all medications out of the reach of children.**

Store at 20°–25°C (68°–77°F); excursions permitted to 15°–30°C (59°–86°F)

[See USP Controlled Room Temperature]