

POLYETHYLENE GLYCOL 3350 AND ELECTROLYTES FOR ORAL SOLUTION, USP

(pol' ee eth' i leen glye' kol 3350)

Read this Medication Guide before you start taking Polyethylene Glycol 3350 and electrolytes for oral solution. This information does not take the place of talking with your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about Polyethylene Glycol 3350 and electrolytes for oral solution?

Polyethylene Glycol 3350 and electrolytes for oral solution and other osmotic bowel preparations can cause serious side effects, including:

Serious loss of body fluid (dehydration) and changes in blood salts (electrolytes) in your blood.

These changes can cause:

- **abnormal heartbeats (arrhythmias) that can cause death.**
- **seizures.** This can happen even if you have never had a seizure.
- **kidney problems.**

Your chance of having fluid loss and changes in body salts with Polyethylene Glycol 3350 and electrolytes for oral solution is higher if you:

- have heart problems.
- have kidney problems.
- take water pills or non-steroidal anti-inflammatory drugs (NSAIDs).

Tell your healthcare provider right away if you have any of these symptoms of a loss of too much body fluid (dehydration) while taking Polyethylene Glycol 3350 and electrolytes for oral solution:

- vomiting that prevents you from keeping down the solution.
- dizziness.
- urinating less often than normal.
- headache.

See Section "What are the possible side effects of Polyethylene Glycol 3350 and electrolytes for oral solution" for more information about side effects.

What is Polyethylene Glycol 3350 and electrolytes for oral solution?

Polyethylene Glycol 3350 and electrolytes for oral solution is a prescription medicine used by adults to clean the colon before a colonoscopy or barium enema X-ray examination. Polyethylene Glycol 3350 and electrolytes for oral solution cleans your colon by causing you to have diarrhea (loose stools). Cleaning your colon helps your healthcare provider see the inside of your colon more clearly during your colonoscopy.

It is not known if Polyethylene Glycol 3350 and electrolytes for oral solution is safe and effective in children.

Who should not take Polyethylene Glycol 3350 and electrolytes for oral solution?

Do not take Polyethylene Glycol 3350 and electrolytes for oral solution if your healthcare provider has told you that you have:

- a blockage in your bowel (obstruction).
- an opening in the wall of your stomach or intestine (bowel perforation).
- a very dilated intestine (toxic megacolon).
- problems with food and fluid emptying from your stomach (gastric retention).
- a problem with food moving too slowly through your intestines (ileus).
- an allergy to any of the ingredients in Polyethylene Glycol 3350 and electrolytes for oral solution. See the end of this Medication Guide for a complete

list of ingredients in Polyethylene Glycol 3350 and electrolytes for oral solution.

What should I tell my healthcare provider before taking Polyethylene Glycol 3350 and electrolytes for oral solution?

Before you take Polyethylene Glycol 3350 and electrolytes for oral solution, tell your healthcare provider if you:

- have heart problems.
- have stomach or bowel problems.
- have ulcerative colitis.
- have problems with swallowing or gastric reflux.
- have a history of seizures.
- are withdrawing from drinking alcohol.
- have a low blood salt (sodium) level.
- have kidney problems.
- have any other medical conditions.
- are pregnant. It is not known if Polyethylene Glycol 3350 and electrolytes for oral solution, will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant.
- are breastfeeding or plan to breastfeed. It is not known if Polyethylene Glycol 3350 and electrolytes for oral solution, passes into your breast milk. You and your healthcare provider should decide if you will take Polyethylene Glycol 3350 and electrolytes for oral solution, while breastfeeding.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Polyethylene Glycol 3350 and electrolytes for oral solution may affect how other medicines work.

Do not take medicines by mouth within 1 hour of starting Polyethylene Glycol 3350 and electrolytes for oral solution or after you start taking Polyethylene Glycol 3350 and electrolytes for oral solution. **Especially tell your healthcare provider if you take:**

- medicines for blood pressure or heart problems.
- medicines for kidney problems.
- medicines for seizures.
- water pills (diuretics).
- non-steroidal anti-inflammatory medicines (NSAID) pain medicines.
- laxatives.
- starch-based thickeners. For patients who have trouble swallowing, do not mix Polyethylene Glycol 3350 and electrolytes for oral solution with starch-based thickeners.

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure if you are taking any of the medicines listed above. Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take Polyethylene Glycol 3350 and electrolytes for oral solution?

You must read, understand, and follow these instructions to take Polyethylene Glycol 3350 and electrolytes for oral solution the right way.

- Take Polyethylene Glycol 3350 and electrolytes for oral solution exactly as your healthcare provider tells you to take it.
- See the "Instructions for Use" on the bottle label for instructions on how to mix, take or give Polyethylene Glycol 3350 and electrolytes for oral solution.
- **Do not take undissolved Polyethylene Glycol 3350 and electrolytes for oral solution powder that has not been mixed with water (diluted). It may increase your risk of nausea, vomiting and fluid loss (dehydration).**
- Do not take other laxatives while taking Polyethylene Glycol 3350 and electrolytes for oral solution.

- Drink reconstituted solution at a rate of 8 ounces (240 ml) every 10 minutes. Rapid drinking of each portion is better than drinking small amounts.
- **Do not eat or drink anything colored red or purple.**
- **Do not eat solid foods at least 2 hours before taking Polyethylene Glycol 3350 and electrolytes for oral solution.** You may eat a light breakfast 2 hours before taking Polyethylene Glycol 3350 and electrolytes for oral solution. For best results, do not consume solid food for 3 to 4 hours before drinking Polyethylene Glycol 3350 and electrolytes for oral solution.
- Drink only water and clear liquids:
 - o the day before your colonoscopy
 - o while taking Polyethylene Glycol 3350 and electrolytes for oral solution
 - o after taking Polyethylene Glycol 3350 and electrolytes for oral solution until 2 hours before your colonoscopy.
- Drink clear liquids before, during, and after you take Polyethylene Glycol 3350 and electrolytes for oral solution to avoid fluid loss (dehydrated). Examples of clear liquids are:
 - o water
 - o clear broth
 - o clear fruit juices without pulp including apple, white grape, or white cranberry
 - o clear soda
 - o strained limeade or lemonade
 - o gelatin (without added fruit or topping)
 - o coffee or tea (Do not use any dairy or non-dairy creamer)
 - o popsicles without pieces of fruit or fruit pulp
- You may experience some abdominal bloating and distention before the bowels start to move. If severe discomfort or distention occur, slow or temporarily stop (discontinue) drinking the solution and contact your healthcare provider.
- The first bowel movement should occur approximately one hour after you start drinking the solution.
- Continue drinking until the watery stool is clear and free of solid matter.

What are the possible side effects of Polyethylene Glycol 3350 and electrolytes for oral solution?

Polyethylene Glycol 3350 and electrolytes for oral solution can cause serious side effects, including:

- **See Section “What is the most important information I should know about Polyethylene Glycol 3350 and electrolytes for oral solution?”**
- **changes in certain blood tests.** Your healthcare provider may do blood tests after you take Polyethylene Glycol 3350 and electrolytes for oral solution to check your blood for changes. Tell your healthcare provider if you have any symptoms of too much fluid loss, including:
 - vomiting
 - nausea
 - bloating
 - dizziness
 - stomach (abdominal) cramping
 - headache
 - urinate less than usual
 - trouble drinking clear liquid
- **ulcers of the bowel or bowel problems (ischemic colitis).** Tell your healthcare provider right away if you have severe stomach-area (abdomen) pain or rectal bleeding.

The most common side effects of Polyethylene Glycol 3350 and electrolytes for oral solution, USP include:

- nausea
- stomach (abdominal) fullness
- bloating
- stomach (abdominal) cramps
- vomiting
- chest x-ray that shows water in the lungs (infiltrate) after vomiting or inhaling food or liquid (aspirate).

- anal irritation
- esophageal bleeding

Tell your healthcare provider if you have any side effect that bothers you or that does not go away.

These are not all the possible side effects of Polyethylene Glycol 3350 and electrolytes for oral solution. For more information, ask your healthcare provider or pharmacist. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store Polyethylene Glycol 3350 and electrolytes for oral solution, USP?

- Store Polyethylene Glycol 3350 and electrolytes for oral solution, USP at room temperature, between 59°F to 86°F (15°C to 30°C).
- Store mixed (reconstituted) solution of Polyethylene Glycol 3350 and electrolytes for oral solution at 36° to 46°F (2°C to 8°C). Do not freeze.
- Use mixed (reconstituted) solution of Polyethylene Glycol 3350 and electrolytes for oral solution within 48 hours.
- After 48 hours, throw away (discard) any mixed (reconstituted) solution of Polyethylene Glycol 3350 and electrolytes for oral solution that is not used.

Keep Polyethylene Glycol 3350 and electrolytes for oral solution, USP and all medicines out of the reach of children.

General information about the safe and effective use of Polyethylene Glycol 3350 and electrolytes for oral solution.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Polyethylene Glycol 3350 and electrolytes for oral solution, USP for a condition for which it was not prescribed. Do not give Polyethylene Glycol 3350 and electrolytes for oral solution, USP to other people, even if they are going to have the same procedure you are. It may harm them.

This Medication Guide summarizes important information about Polyethylene Glycol 3350 and electrolytes for oral solution. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information that is written for healthcare professionals.

For more information, go to www.strides.com or call toll free number 1-877-244-9825.

What are the ingredients in Polyethylene Glycol 3350 and electrolytes for oral solution, USP?

Polyethylene Glycol 3350 and electrolytes for oral solution, USP comes in a 5-liter jug with polyethylene glycol 3350, sodium sulfate, sodium bicarbonate, sodium chloride, and potassium chloride powder.

Active ingredients: polyethylene glycol 3350, sodium sulfate, sodium bicarbonate, sodium chloride, and potassium chloride.

Inactive ingredients: Lemon and Orange Flavored Polyethylene Glycol 3350 and electrolytes for oral solution, USP **only** (acesulfame potassium, natural orange flavor powder, natural flavor lemon powder).

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