

Medication Guide

Colyte® (co-light) with Flavor Packs (peg-3350 & electrolytes for oral solution)

Read this Medication Guide before you start taking Colyte. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about Colyte?

Colyte 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 that can cause death**
- **seizures.** This can happen even if you have never had a seizure.
- **kidney problems**

Your risk of having fluid loss and changes in body salts with Colyte is higher if you:

- have heart problems
- have kidney problems
- take water pills (diuretics) 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 Colyte:

- vomiting
- urinating less often than normal
- dizziness
- headache

See “What are the possible side effects of Colyte?” for more information about side effects.

What is Colyte?

Colyte is a prescription medicine used to clean the colon before a colonoscopy or barium enema X-ray examination. Colyte cleans your colon by causing you to have diarrhea. Cleaning your colon helps your healthcare provider see the inside of your colon more clearly during your colonoscopy or barium enema X-ray examination.

It is not known if Colyte is safe and effective in children.

Who should not take Colyte?

Do not take Colyte if your healthcare provider has told you that you have:

- a blockage in your intestine (bowel obstruction)
- an opening in the wall of your stomach or intestine (bowel perforation)
- problems with food and fluid emptying from your stomach (gastric retention)
- a very dilated intestine (toxic megacolon)
- an allergy to any of the ingredients in Colyte. See the end of this leaflet for a complete list of ingredients in Colyte.

What should I tell my healthcare provider before taking Colyte?

Before you take Colyte, tell your healthcare provider if you:

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

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

Colyte may affect how other medicines work. Medicines taken by mouth may not be absorbed properly when taken within 1 hour before the start of Colyte.

Especially tell you 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 (NSAID) pain medicines
- laxatives

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 Colyte?

See the Instructions for Use at the end of this Medication Guide for dosing instructions. You must read, understand, and follow these instructions to take Colyte the right way.

- **Take Colyte exactly as your healthcare provider tells you to take it.**
- The powder in the Colyte container must be mixed with water (diluted) before drinking. **Do not take Colyte that has not been mixed with water, it may increase your risk of nausea, vomiting and fluid loss (dehydration).**

- Do not eat any solid foods 3 hours before you start taking Colyte, while taking Colyte, and 2 hours after taking Colyte.
- Drink clear liquids before you start taking Colyte, while you take Colyte and after you finish taking Colyte to help prevent fluid loss (dehydration). Examples of clear liquids are:
 - water
 - clear fruit juices without pulp including apple, white grape, or white cranberry
 - strained limeade or lemonade
 - coffee or tea (Do not use any dairy or non-dairy creamer)
 - clear broth
 - clear soda
 - gelatin (without added fruit or topping)
 - popsicles without pieces of fruit or fruit pulp

Do not eat or drink anything colored red or purple.

- **Do not eat or drink anything 2 hours before your colonoscopy or barium enema X-ray examination.**
- You should have your first bowel movement about 1 hour after you start taking Colyte. Continue to take Colyte according to the Instructions for Use until your stool is clear, watery, and has no solid material in it.
- Do not take other laxatives while taking Colyte.
- Stop drinking Colyte solution temporarily or allow for longer time between each dose if you have stomach discomfort, pain or bloating until your symptoms improve. If symptoms continue, tell your healthcare provider.

What are the possible side effects of Colyte?

Colyte can cause serious side effects, including:

- See "**What is the most important information I should know about Colyte?**"
- **changes in certain blood tests.** Your healthcare provider may do blood tests after you take Colyte to check your blood for changes. Tell your healthcare provider if you have any symptoms of too much fluid loss, including:
 - o vomiting
 - o nausea
 - o bloating
 - o dizziness
 - o stomach-area (abdomen) cramping
 - o headache
 - o urinate less than usual
 - o trouble drinking clear liquid
- **ulcers of the 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 Colyte include:

- nausea
- stomach-area (abdomen) fullness and bloating

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 Colyte. 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 Colyte?

- Store Colyte at 68°F to 77°F (20°C to 25°C).
- Store Colyte that has been mixed with water in the refrigerator.
- Use Colyte within 48 hours after mixing with water. Safely throw away any Colyte that you do not use.

Keep Colyte and all medicines out of the reach of children.

General information about the safe and effective use of Colyte.

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

This Medication Guide summarizes the most important information about Colyte. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Colyte that is written for health professionals.

For more information about Colyte, call 1-866-210-5953.

What are the ingredients in Colyte?

Active ingredients: polyethylene glycol (PEG) 3350, sodium chloride, potassium chloride, sodium bicarbonate, sodium sulfate

Inactive ingredients: Flavor packs ingredients:

Lemon lime flavor pack: hypromellose, natural and artificial lemon lime powder, Prosweet® Powder Natural, saccharin sodium, colloidal silicon dioxide

Cherry flavor pack: hypromellose, artificial cherry powder, saccharin sodium, colloidal silicon dioxide

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Colyte can be taken with or without a flavor pack. If you use a flavor pack, complete Steps 1 through 8. If you do not use a flavor pack, throw away the flavor packs and complete Steps 4 through 8.

Step 1: Remove the cap from the Colyte bottle.

Step 2: Tear open 1 flavor pack of your choice and pour contents into the Colyte bottle. Throw away the unused flavor pack.

Step 3: Replace the cap on the Colyte bottle. Shake the Colyte bottle well to mix the contents of the flavor pack into the powder.

Step 4: Remove the cap from the Colyte bottle. Add water to the top of the line on the Colyte bottle marked "FILL TO TOP OF LINE 4 LITERS".

Step 5: Replace the cap on the Colyte bottle tightly and shake the Colyte bottle well to dissolve the powder.

No other ingredients should be added to the Colyte bottle.

Step 6: Refrigerate the Colyte solution until you are ready to drink it. The Colyte solution should be used within 48 hours after mixing.

Step 7: Drink one 8 ounce glass of Colyte solution every 10 minutes. It is best to drink each glass of Colyte solution quickly, instead of sipping it slowly. Continue drinking one 8 ounce glass of Colyte solution every 10 minutes until your stool is clear, watery, and has no solid material in it. This normally requires drinking 3 to 4 liters of Colyte solution to clean your colon. The Colyte bottle should be empty or have less than 1 liter of Colyte solution remaining when your colon cleaning is completed.

Step 8: Safely throw away any Colyte solution that you do not use.

This Medication Guide and Instructions for Use have been approved by the U.S. Food and Drug Administration.

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