

Medication Guide

HalfLytely (haf-LITE-lee) and Bisacodyl (BIS-a-CO-dil) Tablet[®] Bowel Prep Kit

(PEG-3350, sodium chloride, sodium bicarbonate and potassium chloride for oral solution and bisacodyl delayed release tablet)

Read this Medication Guide before you start taking HalfLytely and Bisacodyl Tablet Bowel Prep Kit. 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 HalfLytely and Bisacodyl Tablet Bowel Prep Kit?

HalfLytely and Bisacodyl Tablet Bowel Prep Kit 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:

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

Your chance of having fluid loss and changes in body salts with HalfLytely and Bisacodyl Tablet Bowel Prep Kit 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 HalfLytely and Bisacodyl Tablet Bowel Prep Kit:

- dizziness
- urinating less often than normal
- headache

See “What are the possible side effects of HalfLytely and Bisacodyl Tablet Bowel Prep Kit?” for more information about side effects.

What is HalfLytely and Bisacodyl Tablet Bowel Prep Kit?

HalfLytely and Bisacodyl Tablet Bowel Prep Kit is a prescription medicine used by adults to clean the colon before a colonoscopy. HalfLytely and Bisacodyl Tablet Bowel Prep Kit 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.

It is not known if HalfLytely and Bisacodyl Tablet Bowel Prep Kit is safe and effective in children.

Who should not take HalfLytely and Bisacodyl Tablet Bowel Prep Kit?

Do not take HalfLytely and Bisacodyl Tablet Bowel Prep Kit 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)
- problems with food and fluid emptying from your stomach (gastric retention)
- a very dilated intestine (bowel)
- an allergy to any of the ingredients in HalfLytely and Bisacodyl Tablet Bowel Prep Kit. See the end of this leaflet for a complete list of ingredients in HalfLytely and Bisacodyl Tablet Bowel Prep Kit.

What should I tell my healthcare provider before taking HalfLytely and Bisacodyl Tablet Bowel Prep Kit?

Before you take HalfLytely and Bisacodyl Tablet Bowel Prep Kit, 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 HalfLytely and Bisacodyl Tablet Bowel Prep Kit 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 HalfLytely and Bisacodyl Tablet Bowel Prep Kit passes into your breast milk. You and your healthcare provider should decide if you will take HalfLytely and Bisacodyl Tablet Bowel Prep Kit while breastfeeding.

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

HalfLytely and Bisacodyl Tablet Bowel Prep Kit may affect how other medicines work. Medicines taken by mouth may not be absorbed properly when taken within 1 hour before the start of HalfLytely and Bisacodyl Tablet Bowel Prep Kit.

Especially tell your healthcare provider if you take:

- medicines for blood pressure or heart problems
- medicines for kidney problems
- medicines for depression
- water pills (diuretics)
- non-steroidal anti-inflammatory medicines (NSAID) pain medicines
- laxatives
- antacids

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 HalfLytely and Bisacodyl Tablet Bowel Prep Kit?

See the Patient Directions on the outer product carton for dosing instructions. You must read, understand, and follow these instructions to take HalfLytely and Bisacodyl Tablet Bowel Prep Kit the right way.

- Take HalfLytely and Bisacodyl Tablet Bowel Prep Kit exactly as your healthcare provider tells you to take it.
- Do not take other laxatives while taking HalfLytely and Bisacodyl Tablet Bowel Prep Kit.
- Do not take antacids within 1 hour of taking the Bisacodyl tablet.
- Do not chew or crush the Bisacodyl tablet. Take the tablet with water.
- Do not eat solid foods while taking HalfLytely and Bisacodyl Tablet Bowel Prep Kit. Only clear liquids are allowed while taking and after taking HalfLytely and Bisacodyl Tablet Bowel Prep Kit until your colonoscopy.
- Stop drinking HalfLytely solution temporarily or allow for longer time between each dose if you have stomach discomfort, pain or bloating until your symptoms improve.

- Stop taking HalfLyteLy and Bisacodyl Tablet Bowel Prep Kit and call your healthcare provider right away if you develop hives or a rash. These may be signs of an allergic reaction.

What are the possible side effects of HalfLyteLy and Bisacodyl Tablet Bowel Prep Kit?

HalfLyteLy and Bisacodyl Tablet Bowel Prep Kit can cause serious side effects, including:

- **See “What is the most important information I should know about HalfLyteLy and Bisacodyl Tablet Bowel Prep Kit?”**
- **changes in certain blood tests.** Your healthcare provider may do blood tests after you take HalfLyteLy and Bisacodyl Tablet Bowel Prep Kit 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
- **heart problems. HalfLyteLy and Bisacodyl Tablet Bowel Prep Kit may cause irregular heartbeats.**
- **seizures**
- **decreased blood flow to the intestine (ischemic colitis).** There have been reports of ischemic colitis in people who have taken HalfLyteLy and Bisacodyl Tablet Bowel Prep Kit at higher doses. Tell your healthcare provider right away if you have severe stomach (abdominal) pain or rectal bleeding. These may be symptoms of ischemic colitis.

The most common side effects of HalfLyteLy and Bisacodyl Tablet Bowel Prep Kit include:

- discomfort
- bloating
- stomach (abdominal) cramping
- nausea
- vomiting

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 HalfLytely and Bisacodyl Tablet Bowel Prep Kit. 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 HalfLytely and Bisacodyl Tablet Bowel Prep Kit?

- Store HalfLytely and Bisacodyl Tablet Bowel Prep Kit at room temperature, between 59°F to 86° (15°C to 30°C).
- HalfLytely solution that has been mixed with water may be refrigerated. Mixed solution should be taken within 48 hours.

Keep HalfLytely and Bisacodyl Tablet Bowel Prep Kit and all medicines out of the reach of children.

General information about the safe and effective use of HalfLytely and Bisacodyl Tablet Bowel Prep Kit.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use HalfLytely and Bisacodyl Tablet Bowel Prep Kit for a condition for which it was not prescribed. Do not give HalfLytely and Bisacodyl Tablet Bowel Prep Kit 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 HalfLytely and Bisacodyl Tablet Bowel Prep Kit. 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.braintreelabs.com or call 1-800-874-6756.

What are the ingredients in HalfLytely and Bisacodyl Tablet Bowel Prep Kit?

Active ingredients bisacodyl tablet: bisacodyl.

Inactive ingredients bisacodyl tablet: lactose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, Eudragit L 30-55, polyethylene glycol 400, talc, gelatin, calcium sulfate, confectioners sugar, kaolin, sucrose, Opalux pink, beeswax, and carnauba wax.

Active ingredients HalfLyteLy solution: polyethylene glycol 3350, sodium chloride, sodium bicarbonate, potassium chloride.

Inactive ingredients HalfLyteLy solution: cherry, lemon-lime, orange and pineapple flavor packs.

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This Medication Guide has been approved by the U.S. Food and Drug Administration.

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