

Medication Guide

PREPOPIK (prep-ō-pik)

(sodium picosulfate, magnesium oxide and anhydrous citric acid) for oral solution

Read this Medication Guide instructions before you start taking PREPOPIK and each time you get a refill. There may be new information. 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 PREPOPIK?

PREPOPIK and other 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 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 blood salts with PREPOPIK 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 PREPOPIK:

- vomiting that prevents you from keeping down the additional prescribed amounts of clear liquids that you must drink after taking your PREPOPIK
- dizziness
- urinating less often than normal
- headache

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

What is PREPOPIK?

PREPOPIK is a prescription medicine used by adults to clean the colon before a colonoscopy. Prepopik 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 PREPOPIK is safe and effective in children.

Who should not take PREPOPIK?

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

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

What should I tell my healthcare provider before taking PREPOPIK?

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

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

Tell your healthcare provider about all the medicines you take,

including prescription and non-prescription medicines, vitamins, and herbal supplements.

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

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)
- nonsteroidal anti-inflammatory medicines (pain medicines)
- medicines for depression or mental health problems
- laxatives
- the following medicines should be taken at least 2 hours before starting PREPOPIK and not less than 6 hours after taking PREPOPIK:
 - tetracycline
 - fluoroquinolone antibiotics
 - iron
 - digoxin (Lanoxin)
 - chlorpromazine
 - penicillamine (Cuprimine, Depen)

Ask your healthcare provider or pharmacist for a list of these medicines if you are not sure if you are taking 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 PREPOPIK?**See the Instructions for Use on the outer product carton for dosing. You must read, understand, and follow these instructions to take PREPOPIK the right way.**

- **Take PREPOPIK exactly as your healthcare provider tells you to take it.** Your healthcare provider will prescribe the Split-Dosing option or the Day Before Dosing option, depending on colonoscopy scheduling, distance traveled, and other personal circumstances.
- A complete preparation requires 2 packets of PREPOPIK for oral solution taken separately, each followed by additional fluids.
- It is important for you to drink the additional prescribed amount of clear liquids after taking PREPOPIK to prevent fluid loss (dehydration).

- Examples of clear liquids include water, clear broth, apple juice, white cranberry juice, white grape juice, and ginger ale, plain jello (not red or purple) and frozen juice bars(not purple or red).
- Do not eat solid foods or drink milk while taking PREPOPIK
- Drink clear liquids until your colonoscopy.
- Do not take other laxatives while taking PREPOPIK.
- Stop drinking PREPOPIK temporarily or allow for longer time between each dose if you have bloating, distension, or stomach (abdominal) pain until your symptoms improve.
- Stop taking PREPOPIK and, and call your healthcare provider right away if you develop hives or rash after you take your first packet of PREPOPIK. These may be signs of an allergic reaction.

See the Instructions for Use on the outer product carton for dosing. You must read, understand, and follow these instructions to take PREPOPIK the right way.

1) Split-Dose (evening-before and day of the procedure) Dosing

Take your first packet of PREPOPIK the night before your colonoscopy, and take your second dose the next day, in the morning before your colonoscopy.

On the day before your colonoscopy procedure – 1 packet:

- Dissolve 1 packet of powder in 5 ounces of cold water in the evening, followed by five 8-ounce drinks (upper line on the dosing cup) of clear liquids before bed.

On the day of the colonoscopy procedure – 1 packet:

- Dissolve 1 packet of powder in 5 ounces of cold water in the morning (5 hours before the colonoscopy), followed by at least three 8-ounce drinks of clear liquids before the colonoscopy.

You may continue to drink clear liquids until 2 hours before the time of the colonoscopy.

2) Day-Before (afternoon and evening-before the procedure) Dosing

Take your first PREPOPIK packet in the afternoon or early evening and take your second packet 6 hours later, the night before the colonoscopy.

On the day before the colonoscopy procedure – 2 packets:

- Dissolve 1 packet of powder in 5 ounces of cold water in the afternoon or early evening, followed by five 8-ounce drinks (upper line on the dosing cup) of clear liquids before the next dose.
- Dissolve 1 packet of powder in 5 ounces of cold water in the late evening (followed by three 8-ounce drinks (upper line on the dosing cup) of clear liquids before bed.

You may continue to drink clear liquids until 2 hours before the time of the colonoscopy.

What are the possible side effects of PREPOPIK?

PREPOPIK can cause serious side effects, including:

See “**What is the most important information I should know about PREPOPIK?**”

- **changes in certain blood tests.** Your healthcare provider may do blood tests after you take PREPOPIK 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

- Urinate less than usual
- Trouble drinking clear liquids
- Troubles swallowing
- Seizures
- Heart problems (arrhythmia). PREPOPIK may cause irregular heartbeats
- Ulcers of the bowel or bowel problems (ischemic colitis). Tell your healthcare provider right away if you have severe stomach (abdominal) pain or rectal bleeding. These may be symptoms of decreased blood flow to the intestine.

The most common side effects of PREPOPIK include:

- nausea
- headache
- 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 PREPOPIK. 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 PREPOPIK?

- Store PREPOPIK at room temperature, between 68 to 77°F (20 to 25°C).

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

General information about the safe and effective use of PREPOPIK.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use PREPOPIK for a condition for which it was not prescribed. Do not give PREPOPIK 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 PREPOPIK. If you would like more information, talk with your healthcare provider. You can also ask your pharmacist or healthcare provider for information that is written for healthcare professionals.

For more information, go to www.ferring.com or call 1-888-337-7464.

What are the ingredients in PREPOPIK?

Active ingredients: sodium picosulfate, magnesium oxide and anhydrous citric acid

Inactive ingredients: potassium hydrogen carbonate, saccharin sodium, spray dried orange flavor which contains acacia gum, lactose, ascorbic acid and butylated hydroxyanisole

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

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Issued July/2012