MEDICATION GUIDE
CLENPIQ™ (CLEN-pik)
(sodium picosulfate, magnesium oxide, and anhydrous citric acid)
oral solution

Read and understand these Medication Guide instructions **at least 2 days before** your colonoscopy and again before you start taking CLENPIQ.

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

CLENPIQ 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 CLENPIQ 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 CLENPIQ:

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

See "What are the possible side effects of CLENPIQ?" for more information about side effects.

What is CLENPIQ?

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

Do not take CLENPIQ 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 CLENPIQ. See the end of this leaflet for a complete list of ingredients in CLENPIQ.

Before taking CLENPIQ, tell your healthcare provider about all of your medical conditions, including if you:

- have problems with serious loss of body fluid (dehydration) and changes in blood salts (electrolytes).
- have a history of seizures or take medicines for seizures.
- are withdrawing from drinking alcohol or from taking benzodiazepines.
- have low blood salt (sodium) level.
- have kidney problems or take medicines for kidney problems.
- have heart problems.
- have stomach or bowel problems including ulcerative colitis.
- have problems with swallowing or gastric reflux.
- are pregnant. It is not known if CLENPIQ will harm your unborn baby. Talk to your provider if you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if CLENPIQ passes into your breast milk. You and your healthcare provider should decide if you will take CLENPIQ while breastfeeding.

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

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

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. Do **not** take other laxatives while taking CLENPIQ.

The following medicines should be taken at least 2 hours before starting CLENPIQ and not less than 6 hours after taking CLENPIQ:

- 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 CLENPIQ?

See the Instructions for Use for dosing instructions. You must read, understand, and follow these instructions to take CLENPIQ the right way.

- Take CLENPIQ exactly as your healthcare provider tells you to take it.
- CLENPIQ comes ready to drink. It does not need to be mixed with anything else.
- 1 bottle of CLENPIQ equals 1 dose. Two doses of CLENPIQ are required for complete colonoscopy preparation.
- There are 2 different methods for taking CLENPIQ. **It is better** (preferred) to use the **Split-Dose** method. If you cannot do the Split-Dose method, you can take CLENPIQ using the **Day-Before** method. See the instructions for use for more information.
- All people taking CLENPIQ should follow these general instructions starting 1 day **before** your colonoscopy:
  - only drink clear liquids all day and the next day until 2 hours before your colonoscopy. **Stop** drinking all fluids at least 2 hours before the colonoscopy.
  - after taking CLENPIQ if you have any bloating or feeling like your stomach is upset, wait to take your second dose until your stomach feels better.
- **While taking CLENPIQ, do not:**
  - take any other laxatives.
  - take any medicines by mouth (oral) within 1 hour of starting CLENPIQ.
  - eat solid foods, dairy such as milk, or alcohol while taking CLENPIQ and until after your colonoscopy.
  - eat or drink anything colored red or purple.

Contact your healthcare provider right away if after taking CLENPIQ you have severe vomiting, signs of dehydration, changes in consciousness such as feeling confused, delirious or fainting (loss of consciousness) or seizures after taking CLENPIQ.

What are the possible side effects of CLENPIQ?
CLENPIQ can cause serious side effects, including:
See "**What is the most important information I should know about CLENPIQ"?**

- **Changes in certain blood tests**. Your healthcare provider may do blood tests after you take CLENPIQ 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-area (abdomen) cramping
  - urinate less than usual
  - trouble drinking clear liquids
  - troubles swallowing
  - seizures
  - heart problems
- **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 CLENPIQ include:

- nausea
- headache
- vomiting

These are not all the possible side effects of CLENPIQ.
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 CLENPIQ?

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

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

General information about the safe and effective use of CLENPIQ.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use CLENPIQ for a condition for which it was not prescribed. Do not give CLENPIQ to other people, even if they have the same symptoms that you have. It may harm them. You can ask your pharmacist or healthcare provider for information about CLENPIQ that is written for health professionals.

What are the ingredients in CLENPIQ?

CLENPIQ comes in a carton containing 2 bottles, along with an 8-ounce cup for measuring fluids for hydration.
Each bottle contains:
Active ingredients: sodium picosulfate, magnesium oxide, and anhydrous citric acid
Inactive ingredients:
disodium edetate, sodium benzoate, malic acid, sucralose, acesulfame potassium, sodium metabisulfite, sodium hydroxide, cranberry flavor, and water. The cranberry flavor contains maltodextrin, glyceryl triacetate (triacetin) and sodium octenyl succinated starch.

Manufactured by: Ferring Pharmaceuticals Inc.
Parsippany, NJ 07054, USA
8107000049
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For more information, go to www.CLENPIQ.com or call 1-888-337-7464.

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