Medication Guide

VISICOL® (VĬ-zə-käl)

(sodium phosphate monobasic monohydrate, USP and
sodium phosphate dibasic anhydrous, USP)
Tablets

Read the Medication Guide that comes with VISICOL before you start taking it and each time you take it. This Medication Guide does not take the place of talking with your doctor about your condition or your treatment. If you have any questions about VISICOL, ask your doctor or pharmacist.

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

VISICOL can cause serious side effects, including:

Serious kidney problems. Rare, but serious kidney problems can happen in people who take medicines made with sodium phosphate, including VISICOL, to clean your colon before a colonoscopy. These kidney problems can sometimes lead to kidney failure or the need for dialysis for a long time. These problems often happen within a few days, but sometimes may happen several months after taking VISICOL.

Conditions that can make you more at risk for having serious kidney problems with VISICOL include if you:

- lose too much body fluid (dehydration)
- have slow moving bowels
- have bowels blocked with stool (constipation)
- have severe stomach pain or bloating
- have any disease that causes bowel irritation (colitis)
- have kidney disease
- have heart failure
- take water pills or non-steroidal anti-inflammatory drugs (NSAIDS).

Your age may also affect your risk for having kidney problems with VISICOL.

Before you start taking VISICOL, tell your doctor if you:

- have any kidney problems.
- take any medicines for blood pressure, heart disease or kidney disease.

Severe fluid loss (dehydration). People who take medicines that contain sodium phosphate can have severe loss of body fluid, with severe changes in body salts in the blood, and abnormal heart rhythms. These problems can lead to death.

Tell your doctor if you have any of these symptoms of loss of too much body fluid (dehydration) while taking VISICOL:

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

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

What is VISICOL?

VISICOL is a prescription medicine used in adults 18 years and older, to clean your colon before a colonoscopy. VISICOL cleans your colon by causing you to have diarrhea. Cleaning your colon helps your doctor see the inside of your colon more clearly during the colonoscopy.

It is not known if VISICOL is safe and works in children under age 18.

Who should not take VISICOL?

Do not take VISICOL if:

- you have had a kidney biopsy that shows you have kidney problems because of too much phosphate
- you are allergic to sodium phosphate salts or any of the ingredients in VISICOL. See the end of this Medication Guide for a list of ingredients in VISICOL.

What should I tell my doctor before taking VISICOL?

Before taking VISICOL, tell your doctor about all of your medical conditions, including if you have:

- any of the medical conditions listed in the section "What is the most important information I should know about VISICOL?"
- irritation of the bowel (colitis). VISICOL can cause symptoms of irritable bowel disease to flare-up.
- damage to your bowels
- had stomach surgery
- trouble swallowing pills. You may have trouble swallowing VISICOL.
- problems with an abnormal heart beat
- had a recent heart attack or have other heart problems
- symptoms of too much body fluid loss (dehydration) including vomiting, dizziness, urinating less often than normal, or headache
- a history of seizures
- if you drink alcohol
- recently had coronary artery bypass graft surgery (CABG)
- you are on a low salt diet
- are pregnant. It is not known if VISICOL will harm your unborn baby.

Tell your doctor about all the medicines you take, including prescription and non-prescription medicines, vitamins, and herbal supplements. Any medicine that you take close to the time that you take VISICOL may not work as well. Especially tell your doctor if you take:

- water pills (diuretics)
- medicines for blood pressure or heart problems
- medicines for kidney damage
- medicines for pain, such as aspirin or a non-steroidal anti-inflammatory drug (NSAID)
- a medicine for seizures
- antidepressant medicines or a medicine for anxiety
- a laxative for constipation in the last 7 days. You should not take another medicine that contains sodium phosphate while you take VISICOL.

Ask your doctor if you are not sure if your medicine is one that is listed above.

Know the medicines you take. Keep a list of your medicines to show your doctor or pharmacist when you get a new prescription.

How should I take VISICOL?

- Take VISICOL exactly as prescribed by your doctor.
- You will take VISICOL on the evening before your colonoscopy and about 12 hours later, on the day of your colonoscopy, as described below.
- **It is important for you to drink clear liquids before, during, and after taking VISICOL. This may help prevent kidney damage.** Examples of **clear liquids** are water, flavored water, lemonade (no pulp), ginger ale or apple juice. Do not drink any liquids colored purple or red.

- **You must read, understand, and follow these instructions to take VISICOL the right way:**

  On the evening before your colonoscopy, you will take a total of 20 VISICOL tablets, as follows:

  1. Take 3 VISICOL tablets with 8 ounces of **clear liquids**.
  2. **Wait 15 minutes.**
  3. Take 3 more VISICOL tablets with 8 ounces of **clear liquids.**
  4. Repeat steps 2 and 3 above four more times. Make sure you wait 15 minutes after each time.
  5. When you take your last dose of VISICOL, the dose will be 2 tablets with 8 ounces of clear liquids.

  On the day of your colonoscopy, you will take another 20 VISICOL Tablets about, 3-5 hours before your colonoscopy, as follows:

  1. Take 3 VISICOL tablets with 8 ounces of **clear liquids**.
  2. **Wait 15 minutes.**

3. Take 3 more VISICOL tablets with 8 ounces of **clear liquids.**
4. Repeat steps 2 and 3 above four more times. Make sure you wait 15 minutes after each time.
5. When you take your last dose of VISICOL, the dose will be 2 tablets with 8 ounces of clear liquids.

Tell your doctor if you have any of these symptoms while taking VISICOL:

- vomiting, dizziness, or if you urinate less often than normal. These may be signs that you have lost too much fluid while taking VISICOL.
- trouble drinking clear fluids
- severe stomach cramping, bloating, nausea, or headache.

If you take too much VISICOL, call your doctor or get medical help right away.

What should I avoid while taking VISICOL?

- You should not take other laxatives or enemas, especially those made with sodium phosphate, while taking VISICOL.
- You should not use VISICOL if you have already used it in the last 7 days.

What are the possible side effects of VISICOL?

Visicol can cause serious side effects, including:

- See "What is the most important information I should know about VISICOL?
- seizures or fainting (black-outs). People who take a medicine that contains sodium phosphate, such as VISICOL, can have seizures or faint (become unconscious) even if they have not had seizures before. Tell your doctor right away if you have a seizure or faint while taking VISICOL. See "What should I tell my doctor before taking VISICOL?"
- abnormal heart beat (arrhythmia)
- changes in your blood levels of calcium, phosphate, potassium, sodium

The most common side effects of VISICOL are:

- bloating
- stomach area (abdominal) pain
- nausea
- vomiting

These are not all the possible side effects of VISICOL. For more information, ask your doctor or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How do I store VISICOL?

- Store VISICOL at room temperature, between 59º F to 86° F (15º C to 30° C).
- Throw away any VISICOL that is not needed.

- **Keep VISICOL and all medicines out of the reach of children.**

General information about VISICOL

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

This Medication Guide summarizes the most important information about VISICOL. If you would like more information about VISICOL, talk with your doctor or pharmacist. You can ask your doctor or pharmacist for information that is written for healthcare professionals. For more information, call 1-866-669-7597 (toll-free) or go to: www.Salix.com.

What are the ingredients in VISICOL?

Active ingredients: sodium phosphate monobasic monohydrate and sodium phosphate dibasic anhydrous

Inactive ingredients: microcrystalline cellulose, magnesium stearate, and colloidal silicon dioxide

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Revised March 2009

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

VENART-110-2/Mar 2009