

Medication Guide

VISICOL[®] (VĪ-zə-käl)
(sodium phosphate monobasic monohydrate, USP and
sodium phosphate dibasic anhydrous, USP)
Tablets

Read this Medication Guide before you start taking VISICOL and each time you get a new prescription. There may be new information. This Medication Guide does not take the place of talking with your doctor about your medical condition or your treatment.

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 the colon before 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 or kidney problems
- 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 and severe changes in body salts in the blood (electrolytes):

People who take medicines that contain sodium phosphate can have severe loss of body fluid, with severe changes in body salts in the blood.

These changes can be serious and can cause:

- abnormal heart rhythms
- seizures
- kidney problems

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
- impairment of the bowels or bowel function
- had stomach surgery involving stapling or bypass
- significant irritation of the bowels such as toxic megacolon
- 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 you take VISICOL, tell your doctor if you:

- have kidney problems
- have heart problems
- have a history of seizures
- have had stomach surgery
- have stomach or bowel problems
- have ulcerative colitis
- have problems with swallowing or gastric reflux
- drink alcohol or are withdrawing from alcohol use
- have any other medical conditions
- are on a low salt die
- are pregnant. It is not known if VISICOL will harm your unborn baby. Talk to your doctor if you are pregnant or plan to become pregnant
- are breastfeeding or plan to breast-feed. It is not known if VISICOL passes into your breast milk. You and your doctor should decide if you will take VISICOL while breastfeeding

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

VISICOL may affect how other medicines work. Medicines taken by mouth may not be absorbed properly when taken within 1 hour before the start of VISICOL. 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 problems
- medicines for pain, such as aspirin or a non-steroidal anti-inflammatory drug (NSAID)
- medicine for seizures
- 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 or pharmacist if you are not sure if you take any of the medicines 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.
- **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 starting about, 3 to 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.

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, 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?”**
- **Changes in your blood tests.** Your doctor may do blood tests after you take VISICOL to check your levels of calcium, phosphate, potassium, sodium in your blood. Tell your doctor if you have any symptoms of too much fluid loss, including:
 - Vomiting
 - Nausea
- Abnormal heart beat (arrhythmia)
- **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?”**
- **Colonic mucosal ulcerations and ischemic colitis**

The most common side effects of VISICOL are:

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

Tell your doctor if you have any side effect that bothers you or that does not go away.

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 59° F to 86° F (15° 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

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

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