

# PREPARING FOR YOUR COLONOSCOPY



 ***OsmoPrep***<sup>®</sup>

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

***The Tablet Prep***

**[www.TabletPrep.com](http://www.TabletPrep.com)**



**Rx only**

Please see page 8 for Important Safety Information.  
Call your doctor for medical advice if you experience side effects.



# COLONOSCOPY

## THE COLON

The **colon**, also called the large intestine or bowel, is the final 6-foot-long segment of the digestive tract where waste is formed into solid stool. The job of the colon is to complete the digestive process and prepare waste for elimination from the body.

After you swallow food, it travels from the mouth through the esophagus to the stomach. Once broken down, the food moves from the stomach to the small intestine. The small intestine takes the nutrients from food, and the remaining indigestible portion moves into the colon. The colon stores this waste until the next bowel movement removes it from the body.

The colon is difficult to examine because of its shape and location in the body. But when the colon needs to be examined, the best way for a doctor to do so is by colonoscopy.

## WHAT IS A COLONOSCOPY?

A **colonoscopy** is a routine procedure doctors use to examine the colon. This procedure is the best way for a doctor to be able to view the entire colon and diagnose any problems.

The procedure involves the use of a **colonoscope**, a long, thin, flexible instrument connected to a camera and video display monitor. Colonoscopies generally take from 15 minutes to an hour to complete and are relatively safe and pain free. If the physician notices anything of concern during your colonoscopy, a **biopsy** (the removal of a small amount of tissue to examine) may be performed.

There are several reasons your doctor may recommend a colonoscopy, such as blood in the stool, frequent abdominal pain, or a change in bowel habits. In addition to diagnosing gastrointestinal problems, colonoscopies are also used to screen for **colorectal cancer**.

## COLORECTAL CANCER

Colorectal cancer—cancer of the colon or rectum—is the third most frequently diagnosed cancer in the US (excluding skin cancer), but it is unique in that it is preventable with early detection. It is usually slow growing, and the first sign of potential colorectal cancer is often a precancerous polyp or lesion. Since polyps in the colon can develop into cancer, early detection and removal is essential.

Colonoscopy is the key to early detection and prevention. People without elevated risk factors should have their first colonoscopy at the age of 50 and subsequent colonoscopies every 10 years after that. Anyone with identified risk factors, such as a family history of colorectal cancer, should be screened earlier and more frequently. To assess your risk, speak to your physician.

## EARLY DETECTION

Regular screenings and early detection are the most effective ways to fight colorectal cancer. Identifying and removing precancerous polyps and lesions can stop colon cancer before it starts. Even if cancer has developed, the 5-year survival rate when it is treated while still confined to the colon is over 90%.<sup>1</sup>

If you care about someone aged 50 or older, please pass on the importance of colon cancer screening. Ask that person to talk to a physician about scheduling a colonoscopy. It could save a life.



## PREPARATION

### BE PREPARED

Before your colonoscopy, the colon needs to be completely emptied. When waste is left in the colon, the physician cannot see the colon properly. This could lead to a longer and potentially inaccurate exam, which may necessitate a second exam later.

To clean out your colon, you will need to complete a **bowel prep** prior to the procedure. The prep's job is to quickly eliminate solid waste from the digestive tract—another way of saying it causes diarrhea—leaving a clean colon that your physician can examine.

You have several bowel prep choices. Different bowel preps flush out the colon using different methods, so discuss your options with your physician.

### BOWEL PREPARATION OPTIONS

- **Sodium phosphate tablets:** series of tablets, taken with any 8 oz of clear liquid, that draws water into the colon and flushes out waste matter
- **PEG (polyethylene glycol) lavage:** 2 to 4 liters of nonabsorbable liquids that work by a “plunger effect” to push out waste matter. Certain PEG lavage regimens require use of laxatives and liquids in addition to the nonabsorbable solution

A physician's instructions will vary depending on the type of prep prescribed, the time of the colonoscopy procedure, and specific patient characteristics. All preps involve dietary restrictions a day or two before the colonoscopy.

Make sure you completely understand your physician's instructions for the bowel prep—it is an essential part of a successful examination.

## RELIABLE, TOLERABLE TABLETS

OsmoPrep is a regimen of easy-to-swallow, virtually tasteless sodium phosphate tablets taken prior to colonoscopy.

- Is a tolerable regimen with a low incidence of gastrointestinal adverse side effects<sup>2</sup>
- Provides exceptional colon cleansing<sup>3</sup>
- Dosing regimen helps to ensure adequate hydration<sup>3</sup>
- Is preferred by patients—95% of patients who took OsmoPrep would take it again for a future colonoscopy<sup>2</sup>

## THE IMPORTANCE OF HYDRATION

Colon cleansing can cause dehydration, as it causes the body to lose fluids quickly. Those fluids need to be replaced. Staying hydrated before, during, and after your bowel prep is essential. Be sure to ask your doctor or nurse how to ensure appropriate hydration during your procedure.

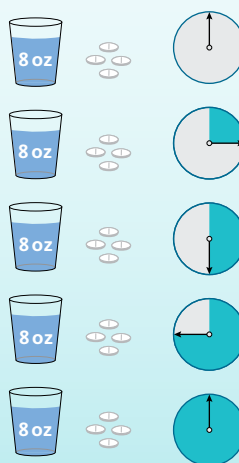
## OSMOPREP® DOSING

Your physician will give you specific instructions for completing the OsmoPrep regimen consisting of a series of 5 doses of 4 tablets, followed by a series of 3 doses of 4 tablets. The tablets are taken with a total of 64 oz of the clear liquid of your choice, such as

- Water
- Apple juice
- Ginger ale
- Sports drink
- Lemonade

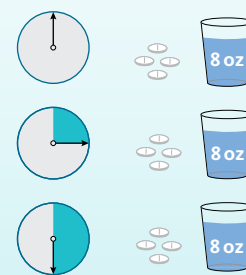
### FIRST REGIMEN

One dose (4 tablets with 8 oz of any clear liquid) every 15 minutes for a total of 5 doses (20 tablets, 40 oz)



### SECOND REGIMEN

One dose (4 tablets with 8 oz of any clear liquid) every 15 minutes for a total of 3 doses (12 tablets, 24 oz)



## IMPORTANT SAFETY INFORMATION

### **What is the most important information I should know about OsmoPrep®?**

OsmoPrep 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 OsmoPrep, 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 OsmoPrep.

Conditions that can make you more at risk for having serious kidney problems with OsmoPrep 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; or take water pills or nonsteroidal anti-inflammatory drugs (NSAIDs).

Your age may also affect your risk for having kidney problems with OsmoPrep. Before you start taking OsmoPrep, tell your doctor if you have kidney problems or take any medicines for blood pressure, heart disease, or kidney disease.

**Severe fluid loss.** 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 OsmoPrep: vomiting, dizziness, urinating less often than normal, or headache. See “What are the possible side effects of OsmoPrep?” for more information about side effects.

### **Who should not take OsmoPrep?**

Do not take OsmoPrep if you have had a kidney biopsy that shows you have kidney problems because of too much phosphate or if you are allergic to sodium phosphate salts or any of the ingredients in OsmoPrep. See the end of this Medication Guide for a list of ingredients in OsmoPrep.

### **What should I tell my doctor before taking OsmoPrep?**

Before taking OsmoPrep, tell your doctor about all 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 OsmoPrep®”: irritation of the bowel (colitis)—OsmoPrep can cause symptoms of irritable bowel disease to flare up; damage to your bowels; problems with 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; had stomach surgery; a history of seizures; if you drink alcohol; are on a low-salt diet; or are pregnant (it is not known if OsmoPrep will harm your unborn baby).

Tell your doctor about all the medicines you take, including prescription and nonprescription medicines, vitamins, and herbal supplements. Any medicine that you take close to the time that you take OsmoPrep 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 nonsteroidal anti-inflammatory drug (NSAID); a 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 OsmoPrep). Ask your doctor if you are not sure if your medicine is listed above.

### **What are the possible side effects of OsmoPrep?**

OsmoPrep can cause serious side effects, including kidney damage and severe fluid loss, seizures or fainting (blackouts)—people who take a medicine that contains sodium phosphate, such as OsmoPrep, 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 OsmoPrep; abnormal heartbeat (arrhythmias); changes in your blood levels of calcium, phosphate, potassium, or sodium.

The most common side effects of OsmoPrep are bloating, stomach area (abdominal) pain, nausea, and vomiting. These are not all the possible side effects of OsmoPrep. 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.

It is recommended that patients receiving OsmoPrep Tablets adequately hydrate before, during, and after the use of OsmoPrep.

Please see accompanying Prescribing Information and Medication Guide for OsmoPrep, including BOXED WARNINGS, located in the pocket.



## QUICK TIPS CHECKLIST

- Talk to your doctor; discuss different bowel prep options and choose the one that is most likely to provide you with a safe, effective, and tolerable prep
- Complete the prep; a clean colon results in the most effective colonoscopy, and your prep is more likely to be thorough if you complete the entire regimen
- Follow your physician's instructions; your physician will provide you with detailed instructions to prepare you for your colonoscopy—follow them exactly
- Stay hydrated; drink at least the amount of fluid required by the prep—hydration before, during, and after the prep and colonoscopy is very important
- Plan for a friend or family member to drive you home; because of the sedatives used during colonoscopy, you will not be allowed to provide your own transportation
- Detach and pass on the provided referral cards to alert those you love that colon cancer is preventable when the early warning signs are detected and treated. The most effective way to detect colon cancer is with a colonoscopy

### DEFINITIONS

**Biopsy:** small amount of tissue removed during colonoscopy for further examination.

**Bowel prep:** regimen prescribed by a physician to clean out the colon.

**Colon:** final 6-foot-long segment of the digestive tract that removes solid waste from the body; also known as the large intestine or bowel.

**Colonoscope:** long, thin, flexible instrument used during colonoscopy that is connected to a camera and video display monitor.

**Colonoscopy:** procedure to examine the colon.

**Colorectal cancer:** cancer that starts in the colon or rectum.

**Hydration:** drinking liquid to restore or maintain fluid balance; an essential component of a safe, effective bowel prep.

### IMPORTANT SAFETY INFORMATION

There have been rare, but serious reports of acute phosphate nephropathy in patients who received oral sodium phosphate products for colon cleansing prior to colonoscopy. Some cases have resulted in permanent impairment of renal function and some patients required long-term dialysis. While some cases have occurred in patients without identifiable risk factors, patients at increased risk of acute phosphate nephropathy may include those with increased age, hypovolemia, increased bowel transit time (such as bowel obstruction), active colitis, or baseline kidney disease, and those using medicines that affect renal perfusion or function (such as diuretics, angiotensin converting enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs], and possibly nonsteroidal anti-inflammatory drugs [NSAIDs]).

It is important to use the dose and dosing regimen as recommended (PM/AM split dose).

OsmoPrep® (sodium phosphate monobasic monohydrate, USP, and sodium phosphate dibasic anhydrous, USP) Tablets are indicated for cleansing of the colon as a preparation for colonoscopy in adults 18 years of age or older.


Considerable caution should be advised before OsmoPrep is used in patients with severe renal insufficiency, congestive heart failure, ascites, unstable angina, gastric retention, ileus, severe chronic constipation, bowel perforation, toxic megacolon, gastric bypass or stapling surgery, or hypomotility syndrome. Use with caution in patients with impaired renal function, patients with a history of seizures or at higher risk of seizure, patients with higher risk of cardiac arrhythmias, known or suspected electrolyte disturbances (such as dehydration), or people taking drugs that affect electrolyte levels. Patients with electrolyte abnormalities such as hypernatremia, hyperphosphatemia, hypokalemia, or hypocalcemia should have their electrolytes corrected before treatment with OsmoPrep.

OsmoPrep is contraindicated in patients with a known allergy or hypersensitivity to sodium phosphate salts or any of its ingredients, and in patients with biopsy-proven acute phosphate nephropathy.

In clinical trials, the most commonly reported adverse reactions (reporting frequency >3%) were abdominal bloating, nausea, abdominal pain, and vomiting. It is recommended that patients receiving OsmoPrep be advised to adequately hydrate before, during, and after the use of OsmoPrep.

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Additional information about colon cancer and the colonoscopy procedure can be found at [www.TabletPrep.com](http://www.TabletPrep.com).

**References:** **1.** Colon cancer statistics. Colon Cancer Alliance Web site. Available at: [http://www.ccalliance.org/what\\_statistics.html](http://www.ccalliance.org/what_statistics.html). Accessed July 28, 2009. **2.** Data on file. Salix Pharmaceuticals, Inc. **3.** OsmoPrep [prescribing information]. Morrisville, NC: Salix Pharmaceuticals, Inc; 2009.



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