

Medication Guide

OsmoPrep® (AhZ-MŌ-prĕp)

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

Tablets

Read this Medication Guide before you start taking OsmoPrep 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 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 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 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 inflammation (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 OsmoPrep.

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

- have 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

(electroytes). 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 OsmoPrep:

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

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

What is OsmoPrep?

OsmoPrep is a prescription medicine used in adults 18 years and older to clean your colon before a colonoscopy. OsmoPrep 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 OsmoPrep is safe and effective in children under age 18.

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.
- 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 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 you take OsmoPrep, 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 diet
- are pregnant. It is not known if OsmoPrep 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 OsmoPrep passes into your breast milk. You and your doctor should decide if you will take OsmoPrep while breastfeeding.

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

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

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 OsmoPrep.

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 OsmoPrep?

- Take OsmoPrep exactly as prescribed by your doctor.
- **It is important for you to drink clear liquids before, during, and after taking OsmoPrep. 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 OsmoPrep the right way:

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

1. Take 4 OsmoPrep tablets with 8 ounces of **clear liquids**.
2. **Wait 15 minutes.**
3. Take 4 more OsmoPrep tablets with 8 ounces of **clear liquids**.
4. Repeat steps 2 and 3 above, three more times. Make sure you wait 15 minutes after each time.

On the day of your colonoscopy, you will take a total of 12 OsmoPrep tablets, starting about 3 to 5 hours before your colonoscopy, as follows:

1. Take 4 OsmoPrep tablets with 8 ounces of **clear liquids**.
2. **Wait 15 minutes.**
3. Take 4 more OsmoPrep tablets with 8 ounces of **clear liquids**.
4. Repeat steps 2 and 3 one more time.

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

What should I avoid while taking OsmoPrep?

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

What are the possible side effects of OsmoPrep?

OsmoPrep can cause serious side effects, including:

- **See “What is the most important information I should know about OsmoPrep?”**
- **Changes in your blood tests.** Your doctor may do blood tests after you take OsmoPrep 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 (arrhythmias)
- **Seizures or fainting (black-outs).** 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.
- **Inflammatory bowel disease.**

The most common side effects of OsmoPrep 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 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.

How should I store OsmoPrep?

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

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

General information about OsmoPrep.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use OsmoPrep for a condition for which it was not prescribed. Do not give OsmoPrep 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 OsmoPrep. If you would like more information about OsmoPrep, 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 OsmoPrep?

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

Inactive ingredients: polyethylene glycol 8000 and magnesium stearate
OsmoPrep is gluten-free.

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

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