



IMPORTANT DRUG WARNING

SUBJECT: Boxed Warning for Prescription Oral Sodium Phosphate Products

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

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

PLEASE FAX COMPLETED FORMS TO (310)273-0314, OR MAIL TO OUR OFFICE

Date: October 15, 2009

Dear Healthcare Professional:

Salix Pharmaceuticals, Inc. would like to inform you of labeling revisions to the OsmoPrep and Visicol U.S. Prescribing Information, to further strengthen and clarify information regarding the risk of acute phosphate nephropathy with the use of these products. A **Boxed Warning** has been added to the prescribing information for OsmoPrep and Visicol as follows:

WARNINGS

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, angiotension converting enzyme [ACE] inhibitors, angiotension receptor blockers [ARBs], and possibly nonsteroidal anti-inflammatory drugs [NSAIDs]). *See WARNINGS.*

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

See DOSAGE and ADMINISTRATION.

I have read the above and following page, am aware of the risks involved using

phosphate preparations, and desire to proceed with a phosphate preparation.

Printed name:

Signature:

Date:

Time:



Patients with increased risk of acute phosphate nephropathy include those with

- Increased age
- Hypovolemia
- Increased bowel transit time (such as bowel obstruction)
- Active colitis
- Baseline kidney disease
- Using medicines that affect renal perfusion or function (e.g. diuretics, angiotensin-converting enzyme [ACE] inhibitors, angiotensin receptor blockers [ARBs], and possibly nonsteroidal anti-inflammatory drugs [NSAIDs]).

OsmoPrep and Visicol should be used with caution in patients with impaired renal function, patients with a history of acute phosphate nephropathy, severe renal insufficiency (creatinine clearance less than 30 mL/minute), known or suspected electrolyte disturbances (e.g., dehydration). Patients with electrolyte abnormalities such as hypernatremia, hyperphosphatemia, hypokalemia, or hypocalcemia should have their electrolytes corrected before treatment.

OsmoPrep or Visicol should NOT be taken by patients who

- Are taking other laxatives, especially those made with sodium phosphate
- Are allergic to sodium phosphate salts or to any of the ingredients in OsmoPrep or Visicol

Before prescribing OsmoPrep or Visicol, you should be aware of your patient's medical concerns, including a history of

- Seizures
- Electrolyte abnormalities such as a hypocalcemia, hypokalemia, hypernatremia, hyperphosphatemia
- Uncontrolled arrhythmias
- Recent myocardial infarction
- Cardiomyopathy
- Prolonged QT
- Congestive heart failure
- Ascites
- Unstable angina
- Gastric retention
- Ileus
- Any damage to the bowel such as acute bowel obstruction, pseudo-obstruction of the bowel, bowel perforation, acute colitis, or toxic megacolon
- Severe chronic constipation
- Gastric bypass or stapling surgery
- Hypomotility syndrome

Additionally, you should be aware if your patients are taking any of the following therapies and use caution in prescribing OsmoPrep or Visicol:

- Seizure medications or medications that lower the seizure threshold such as tricyclic antidepressants
- Laxatives for constipation (in the last week)
- Low-salt diet

Printed name:

Signature: