

RHEINGOLD FIRM OSMOPREP PRESS RELEASE

GREENSBORO, N.C., Dec. 23 /PRNewswire/ -- Suits were commenced Dec. 23, 2009 in North Carolina for four users who allege kidney damage due to the use of OsmoPrep, a prescription drug used to cleanse the intestines in preparation for a colonoscopy. (Holshouser et al v. Salix Pharmaceuticals, Ltd. and Salix Pharmaceuticals, Inc.)

The actions are against two Morrisville, N.C., pharmaceutical companies, Salix Pharmaceuticals, Ltd., and Salix Pharmaceuticals, Inc. (Nasdaq: SLXP). The company, which specializes in marketing gastrointestinal drugs, began selling OsmoPrep in 2006. It had over \$30 million in sales in 2008.

OsmoPrep contains two types of sodium phosphates, which work by drawing water in the bowels. A large number of pills are taken the day before and the day of the colonoscopy. Salix also sells a product, Visicol, with similar chemicals and has the same purpose.

In December 2008, after receiving a number of reports of kidney injury, the FDA required Salix to place a black box warning on the product, as to serious kidney damage occurring after use of OsmoPrep and also Visicol. A black box warning is the strictest type of warning that the FDA can force a drug supplier to use in its labeling.

Also as a condition for continuing to market OsmoPrep, the FDA required Salix to perform what is known as a "REMS" evaluation, Risk Evaluation and Mitigation Strategies. These are designed to determine which population is more at risk in using the product, such as older person, those who are dehydrated or have pre-existing kidney damage, and those concurrently on other drugs.

The liquid form of these oral phosphates had been used in Fleet Phospho-Soda, an over-the-counter product manufactured by C. B. Fleet in Virginia. Fleet withdrew this product from the market in December 2008 in response to a similar request from the FDA to enhance its warnings.

The four plaintiffs in this suit, which was filed in Burke County, N.C., sustained a variety of serious kidney injuries, including the need for dialysis. The medical name for the condition they have suffered is acute phosphate nephropathy.

The complaint alleged that Salix was aware of the risks of serious kidney damage at the time of first marketing OsmoPrep and up until the FDA forced the black box warning. Such information came from articles in the medical literature and individual case reports.

The suit was commenced by the Greensboro, N.C., firm of WardBlackLaw, with assistance of the firm of Rheingold, Valet, Rheingold, Shkolnik and McCartney LLP, of New York City. The Rheingold firm is also involved with the Fleet Phospho-Soda litigation which has been consolidated in Cleveland, OH.

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The FDA issued an alert on December 11th, 2008 stating that it had become aware of reports of acute kidney injury associated with the use of OsmoPrep. This type of kidney injury is known as Acute Phosphate Nephropathy. OsmoPrep is a type of oral sodium phosphate products (OSP) and it is used for bowel cleansing prior to colonoscopy or other procedures. In some cases when used for bowel cleansing, these serious adverse events have occurred in patients without identifiable factors that would put them at risk for developing acute kidney injury. We cannot rule out, however, that some of these patients were dehydrated prior to ingestion of OSPs or they did not drink sufficient fluids after ingesting OSP.

Acute phosphate nephropathy is a form of acute kidney injury that is associated with deposits of calcium-phosphate crystals in the renal tubules that may result in permanent renal function impairment. Acute phosphate nephropathy is a rare, serious adverse event that has been associated with the use of OsmoPrep. The occurrence of these events was previously described in an Information for Healthcare Professionals sheet and an FDA Science Paper issued in May 2006. Additional cases of acute phosphate nephropathy have been reported to FDA and described in the literature since these were issued.

Individuals who appear to have an increased risk of acute phosphate nephropathy following the use of OsmoPrep include persons: who are over age 55; who are hypovolemic or have decreased intravascular volume; who have baseline kidney disease, bowel obstruction, or active colitis; and who are using medications 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]).

As a result of new safety information received, FDA is requiring the manufacturer of OsmoPrep, Salix Pharmaceuticals, Inc. to add a Boxed Warning to the labeling for this product. FDA is also requiring that the manufacturer develop and implement a risk evaluation and mitigation strategy (REMS), which will include a Medication Guide, to ensure that the benefits of OsmoPrep outweighs the risk of acute phosphate nephropathy, and to conduct a postmarketing clinical trial to further assess the risk of acute kidney injury with use of OsmoPrep.

If you or a loved one has been affected by OsmoPrep, please contact our service immediately. We can help put you in touch with experienced attorneys who can help you with your case.

An Attorney For You is a free consumer service. We are not a law firm. We help consumers find the best representation for their legal needs. Our service allows the consumer to review responses by many law firms. This process introduces competition amongst the law firms and allows the consumer to find superior legal representation.

Fill out one simple form and get responses from OsmoPrep Attorneys competing for your case. Email up to 10 law firms in one click; you review the responses in order to choose the right attorney for you.

OsmoPrep Lawsuit Attorney