

From: ASGE  
Subject: **FDA alert: Oral Sodium Phosphate Products - new safety measures required**  
Date: 12/11/2008 3:45:51 PM CST  
To: Kruss Daniel M.  
Reply-To: ASGE



American Society for  
Gastrointestinal Endoscopy

### **FDA Announcement**

#### **Oral Sodium Phosphate (OSP) Products for Bowel Cleansing: reports of acute phosphate nephropathy, Boxed Warning to be added to labeling**

FDA has become aware of reports of acute phosphate nephropathy, a type of acute kidney injury, associated with the use of oral sodium phosphate products (OSP) for bowel cleansing prior to colonoscopy or other procedures. These products include the prescription products, Visicol and OsmoPrep, and OSPs available over-the-counter without a prescription as laxatives (e.g., Fleet Phospho-soda). 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.

FDA is requiring the manufacturer of Visicol and OsmoPrep, the two OSPs available by prescription only, to add a Boxed Warning to the labeling for these products. 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 these products outweigh 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 these products. FDA recommends, in light of the risk of acute phosphate nephropathy, over-the-counter laxative OSP products should not be used for bowel cleansing. Consumers should only use OSPs for bowel cleansing pursuant to a prescription from a healthcare professional.

Read the MedWatch 2008 safety summary, including a link to the FDA Drug Information Page, at:

<http://www.fda.gov/medwatch/safety/2008/safety08.htm#OSP>