

## **NATIONAL PBM COMMUNICATION • December 19, 2008**

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### ***Visicol and OsmoPrep (oral sodium phosphate products) and Acute Phosphate Nephropathy***

- The FDA is requiring that the manufacturers of Visicol and OsmoPrep (oral sodium phosphate products) add:
  - a BOXED WARNING in the prescription product labeling to relay the risk of acute phosphate nephropathy with use of these products;
  - a risk evaluation and mitigation strategy (REMS);
  - a Medication Guide for patients detailing the possible risk of acute kidney injury;
  - a postmarketing clinical trial to further evaluate the risk of developing acute phosphate nephropathy with these products.
- Oral sodium phosphate products (OSP) are used for bowel cleansing in preparation for colonoscopy or other procedures.
- The FDA extends its concerns to the over-the-counter (OTC) products (i.e., Fleet Phospho-soda).
  - Data show no risk of kidney injury when OTC products are used in lower doses as laxatives.
  - OTC products have the same risk as prescription products when used for bowel cleansing at higher doses.
- Since 2006, the FDA has received 20 reports of kidney injury related to OsmoPrep use:
  - 3 cases of acute phosphate nephropathy confirmed by biopsy;
  - Onset of kidney injury in reported cases varied from within several hours of use up to 21 days after use.
- FDA recommends caution when using OSP prescription products in the certain high-risk groups:
  - Patients >55 years of age;
  - Patients with dehydration, kidney disease, acute colitis, or delayed bowel emptying; and
  - Concomitant use with certain medicines that affect kidney function, such as diuretics, angiotensin converting enzyme inhibitors, angiotensin receptor blockers, and possibly nonsteroidal anti-inflammatory drugs (such as ibuprofen and other arthritis medications).<sup>1</sup>
- FDA recommends that patients do not use OTC products for bowel cleansing.

#### REFERENCES

1. FDA. [http://www.fda.gov/cder/drug/infopage/OSP\\_solution/default.htm](http://www.fda.gov/cder/drug/infopage/OSP_solution/default.htm). (Accessed December 11, 2008)

#### **ACTIONS**

- **Facility Director** (or physician designee): Forward this document to the Facility Chief of Staff (COS).
- **Facility COS**: Forward this document to all appropriate providers who prescribe these medications (e.g., **primary care providers, GI specialists, and Radiologists**, including contract providers, etc.). In addition, forward to the Associate Chief of Staff (ACOS) for Research and Development (R&D). Forward to other VA employees as deemed appropriate.
- **ACOS for R&D**: Forward this document to Principal Investigators (PIs) who have authority to practice at the facility and to your respective Institutional Review Board (IRB).