

FDA ALERT REGARDING OSMOPREP

On December 11, 2008, the US Food and Drug Administration (FDA) issued an alert regarding the risk of kidney injury following the use of OsmoPrep pills for bowel cleansing prior to colonoscopy.

At the time that the alert was announced, approximately 20 cases of kidney damage had been reported. To put this in perspective however, it is likely that well over a million prescriptions for OsmoPrep are written annually. The FDA has acknowledged that OsmoPrep is really quite safe overall, and continues to endorse the use of prescription laxatives. The thrust of their concerns involves laxatives that contain large amounts of sodium phosphate. As a result, Fleet Phospho-soda and Fleet EZ-Prep have been voluntarily withdrawn from the market. OsmoPrep pills contain significantly less sodium phosphate than the Fleet products.

Risk factors associated with OsmoPrep pills include patients over 55 years of age, those with underlying kidney impairment or severe constipation. Certain medications that affect blood flow to the kidney may also increase the risk. These include anti-inflammatory pain relievers and certain blood pressure lowering drugs (see below).

OsmoPrep should never be used for colonoscopy preparation if you have a history of kidney disease, have had one of your kidneys surgically removed, or have congenital absence of one of your kidneys.

Pre-colonoscopy blood tests to check kidney function and electrolytes *may* be recommended (unless similar studies have been ordered by your primary care physician within a month or so of your exam).

Neither the FDA nor the drug manufacturer formally recommends pre-colonoscopy blood tests at this time.

Aggressive oral hydration as defined in our colonoscopy instruction packet is THE most important factor in the prevention of kidney injury.

Antihypertensive Agents of Concern According to the FDA

Benazepril (Lotensin)	Moexipine (Univasc)
Candesartan (Atacand)	Olmesartan (Benicar)
Captopril (Capoten)	Perindopril (Aceon)
Enalapril (Vasotec)	Quinapril (Accupril)
Eprosartan (Tevetan)	Ramipril (Altace)
Fosinopril (Monopril)	Telmisartan (Micardis)
Irbesartan (Avalide/Avapro)	Trandolapril (Mavik)
Lisinopril (Prinivil/Zestril)	Valsartan (Diovan)
Losartan (Cozaar/Hyzaar)	

**Some of these drug names may end in HCT

The complete text is available at: http://www.fda.gov/cder/drug/InfoSheets/HCP/OSP_solution2008HCP.htm