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## Colonoscopy Prep Drugs Get New Black-Box Warnings

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For many people, confronting a colonoscopy is a test of both will and modesty but there is no doubt it is a life-saving procedure. Preparation for this procedure starts early and involves both the body and the mind. Preparing the body requires use of drugs to evacuate the intestine and bowel, routine and safe for most people but recent concerns about the safety of two drugs often used for this purpose have led the US Food and Drug Administration (FDA) to strengthen its labeling requirement for them to include its strongest warning, a black box on the label.

Visicol and OsmoPrep must now feature safety concerns outlined in a bold, black box on the label and consumer data sheets that accompany prescriptions. Salix Pharmaceuticals, Morrisville, North Carolina, makes both these oral sodium phosphate medications that are known to cause a severe form of injury to the kidneys called acute phosphate nephropathy. Twenty cases have been reported to the FDA, all attributed to OsmoPrep. Injury begins within several hours after taking it for some patients and others develop symptoms as late as 21 days after use.

In addition to adding the black boxes to their labeling, Salix must develop a strategy for risk evaluation and mitigation, develop and distribute medication guides alerting consumers to the associated risk of kidney damage, and conduct post-marketing clinical trial to assess the drugs' risk of causing injury.

During a teleconference, an FDA spokesperson, Dr. Joyce Korvick, expressed similar concerns for non-prescription Fleet Phospho-soda, made by CB Fleet Co., Lynchburg, Virginia. This product is safe when used as a laxative but should not be used to cleanse the bowel before a colonoscopy or other medical procedures. Strengthened label warnings are also required of this product.

Safe alternatives recommend by Korvick, who is deputy director of the Division of Gastroenterology Products at the FDA's Center for Drug Evaluation and Research, include GoLYTELY and HalfLyte Bowel Prep.

Today's FDA announcement came with the warning against using oral sodium phosphate products on children younger than 18, in combination with other laxatives that contain sodium phosphate, and in individuals at increased risk of kidney injury.

The American Cancer Society lists colorectal cancer as the third most common form of cancer in both men and women, estimating as many as 150,000 new cases in 2008 alone. Routine screening, including colonoscopies, makes this form of cancer one of the earliest to detect and easiest to treat. It is important to understand acute phosphate nephropathy is extremely rare and no one should miss a potentially life-saving colonoscopy because of injury concerns.

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