

## **FDA Safety Alert: Oral Sodium Phosphate (OSP) Products for Bowel Cleansing**

This December 2008, the FDA issued a Safety Alert stating that oral sodium phosphate for colon cleansing prior to colonoscopy should only be available by prescription. As a result, the C. B. Fleet Company (Lynchburg, Virginia) immediately issued a voluntary recall on their over-the-counter products for colon cleansing in the United States. The FDA's issuance followed a review after "it received more than 20 reports of a rare, but serious form of kidney failure among patients taking the drugs, known as oral phosphate products".

Further details can be found at: <http://www.fda.gov/medwatch/safety/2008/safety08.htm#OSP>

In Canada, oral sodium phosphate remains available as an over-the-counter preparation but is no longer recommended for colon cleansing prior to colonoscopy. In light of these developments, Canadian physicians should re-examine whether this product continues to provide the best risk – benefit profile for their patients. This examination must include an assessment of the relative strengths of alternative products for colon cleansing, including combined sodium picosulphate and magnesium citrate (e.g. Pico-salax), large volume polyethylene glycol solutions (e.g. Colyte), and magnesium citrate alone (see review by Barkun et al.<sup>1</sup>). Many Canadian physicians have found that Pico-salax provides reasonable efficacy, is very well tolerated by patients, and appears to have a good safety profile. A recent study<sup>2</sup> has confirmed that this agent is extremely well tolerated by patients, has an excellent safety profile based on careful hemodynamic and biochemical monitoring, and with bisacodyl added as an adjuvant (10 mg each night for two days before Pico-salax administered) provides better cleansing than oral sodium phosphate in the right colon. This agent cannot be used in patients with renal failure and large volume polyethylene solutions (e.g. Colyte) are a safe alternative in this setting. In those instances where physicians still feel that oral sodium phosphate remains the best choice for their patients, a thorough discussion of the rare but serious risk of renal failure should first occur with the patient. A careful screening for suspected risk factors and appropriate steps to mitigate against dehydration should be conducted. A more detailed discussion and related recommendations are in press<sup>3</sup>.

1. Barkun, A. et al. Commonly used preparations for colonoscopy: efficacy, tolerability, and safety—a Canadian Association of Gastroenterology position paper. *Canadian Journal of Gastroenterology* 20:699-710,2006.
2. Hookey, L. and S. Vanner. Picosalax plus bisacodyl is superior to oral sodium phosphate for colon cleansing prior to colonoscopy. *American Journal of Gastroenterology*. In press.
3. Rex, D. and S. Vanner. Oral sodium phosphate for colon cleansing prior to colonoscopy: does it still make sense? *Canadian Journal of Gastroenterology*. In press.