U.S. Food and Drug Administration
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Drug Safety Communications

FDA Drug Safety Communication

FDA warns of possible harm from exceeding recommended dose of over-the-counter sodium phosphate products to treat constipation

Safety Announcement

[1-8-2014] The U.S. Food and Drug Administration (FDA) is warning that using more than one dose in 24 hours of over-the-counter (OTC) sodium phosphate drugs to treat constipation can cause rare but serious harm to the kidneys and heart, and even death. OTC sodium phosphate drug products include oral solutions taken by mouth and enemas used rectally. Consumers and health care professionals should always read the Drug Facts label for OTC sodium phosphate drugs and use these products as recommended on the label, and not exceed the labeled dose. Caregivers should not give the oral products to children 5 years and younger without first discussing with a health care professional. Health care professionals should use caution when recommending an oral dose of these products for children 5 years and younger. The rectal form of these products should never be given to children younger than 2 years.

FDA has become aware of reports of severe dehydration and changes in the levels of serum electrolytes from taking more than the recommended dose of OTC sodium phosphate products, resulting in serious adverse effects on organs, such as the kidneys and heart, and in some cases resulting in death. These serum electrolytes include calcium, sodium, and phosphate. According to the reports, most cases of serious harm occurred with a single dose of sodium phosphate that was larger than recommended or with more than one dose in a day.

Some individuals may be at higher risk for potential adverse events when the recommended dose of OTC sodium phosphate is exceeded. These individuals include young children; individuals older than 55 years; patients who are dehydrated; patients with kidney disease, bowel obstruction, or inflammation of the bowel; and patients who are using medications that may affect kidney function. These medications include diuretics or water pills; angiotensin converting enzyme inhibitors (ACEIs) and angiotensin receptor blockers (ARBs) used to treat high blood pressure; and nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin, ibuprofen, and naproxen.

FDA communicated previously about the risk of kidney injury with the use of oral sodium phosphate drug products at higher doses for bowel cleansing prior to colonoscopy or other procedures. These 2008 communications included an Information for Healthcare Professionals Sheet, an FDA News Release, and a Questions and Answers document.

Facts about over-the-counter (OTC) sodium phosphate drug products

- Used for the relief of occasional constipation.
- Available as a solution for oral or rectal (enema) use.
- Available as single-ingredient drug products, containing either sodium biphosphate or sodium phosphate, and as combination drug products containing both ingredients.
- The recommended dose is a single dose given once a day for not more than 3 days.
- Marketed under the brand-name Fleet, and as store brands and generic products.

Additional Information for Consumers and Parents/Caregivers

- Always read and follow the directions on the Drug Facts labels included on over-the-counter sodium phosphate oral solutions and rectal enemas to find out the correct dose and dosing frequency. Changes in blood electrolyte levels, resulting in serious harm to the kidneys and heart and, more rarely, death, have occurred in adults and children who used more than the recommended dose of OTC sodium phosphate products to treat constipation.
- Do not use more than one dose of these products in 24 hours. Even if you or your children do not have a bowel movement after taking a single oral or rectal dose, do not use another dose within 24 hours. Contact a health care professional for advice.
- Serious harm can occur with use of either the oral or rectal forms of OTC sodium phosphate.
- Do not give these products rectally to children younger than 2 years.
- Do not give these products by mouth to children 5 years and younger without first talking with a health care professional.
- Talk with a health care professional before using these products if you are older than 55 years; have kidney disease, bowel inflammation or bowel obstruction; have heart or kidney failure; are dehydrated; or take certain medications. These medications include diuretics or water pills; angiotensin converting enzyme inhibitors; (ACEIs) or angiotensin receptor blockers (ARBs) to treat high blood pressure, and nonsteroidal anti-inflammatory drugs (NSAIDs) such as aspirin, ibuprofen, and naproxen.
- If you or your child experiences symptoms of kidney injury, seek medical attention immediately and do not take another dose of the product. Symptoms of kidney injury include drowsiness, sluggishness, decreased amount of urine, or swelling of the ankles, feet, and legs.

- Report side effects from OTC sodium phosphate drug products to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Additional Information for Health Care Professionals

- Severe dehydration and electrolyte abnormalities associated with serious complications such as acute kidney injury, arrhythmias, and death have occurred in adults and children who overdosed using oral or rectal over-the-counter (OTC) sodium phosphate solutions to treat constipation.
- The severity of adverse events is similar regardless of the route of sodium phosphate administration. Rectal forms of sodium phosphate drug products should not be considered safer than the oral forms.
- Rectal sodium phosphate drug products should not be used at all in children younger than 2 years.
- Use caution if recommending use of an oral OTC sodium phosphate drug product in children 5 years and younger.
- Avoid exceeding the maximum recommended rectal or oral dose of sodium phosphate products for both children and adults.
- Additional doses are not recommended within 24 hours for patients who do not have a bowel movement after taking an oral or rectal dose.
- Avoid concomitant treatment with laxatives containing sodium phosphate.
- Use caution when recommending these products to patients at potentially higher risk for product-related adverse events. These include those older than 55 years; patients with hypovolemia; or decreased intravascular volume; those who have baseline kidney disease, decreased bowel transit time, bowel obstruction, or active colitis; and those who are using medications that affect renal perfusion or function, such as diuretics, ACEIs, ARBs, or NSAIDs.
- Advise patients to ensure they are adequately hydrated during product use. Assess serum electrolytes and renal function in patients who may be at higher risk for product-related adverse events, which includes those who have retained a rectal dose for more than 30 minutes, who are vomiting, or who may have signs of dehydration.
- Report adverse events involving OTC sodium phosphate drug products to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of this page.

Data Summary

FDA reviewed the FDA Adverse Event Reporting System (FAERS) database from 1969 through 2012 and the medical literature from 1957 through August 2013 for cases describing serious adverse events associated with the oral or rectal use of over-the-counter (OTC) sodium phosphate drug products used to treat constipation. We identified 54 cases describing serious adverse events in 25 adults and in 29 children. Ten cases were reported to the FAERS database and 44 were published in the medical literature.[1-39] The age of the consumers ranged widely from 8 days to 97 years, but most cases involved older adults and children younger than 5 years. Nearly two-thirds of the adults and nearly half of the children in whom adverse events were reported had one or more of the following:

- Dehydration, kidney disease, acute colitis, or delayed bowel emptying
- Concomitant use of drugs that act on renal function, including diuretics, ACEIs, ARBs, and NSAIDs

All reports of serious outcomes were characterized by dehydration and/or electrolyte disturbances with associated complications such as acute kidney injury and death. The severity of adverse events was similar regardless of whether the products were administered orally or rectally. The predominant electrolyte disturbances were hyperphosphatemia, hypocalcemia, and hypernatremia. Nearly half (12/25) of adult cases and 3% (1/29) of pediatric cases reported a fatal outcome. The remaining non-fatal cases were life-threatening in more than two-thirds of affected adults and in all of the affected children. These included acute deterioration in respiratory status, mental status, and heart function. Four adults required dialysis and two underwent surgery for suspected bowel perforation. Three children required dialysis, including two younger than 2 years. Two children developed abdominal distention significant enough to require surgery. One child younger than 2 years had residual neurological defects.

In the 50 cases for which the administered dose was reported (27 pediatric, 23 adult), serious adverse events occurred in patients who took a dose in excess of the labeled amount, including 60% (16/27) of the pediatric cases and 70% (16/23) of the adult cases. Adults and pediatric patients who overdosed either received a single dose that contained a greater amount of sodium phosphate than recommended on the label, or they received the product more frequently than recommended on the label. The duration of use in the majority of the overdose cases was 1 to 2 days. Forty percent (11/27) of the pediatric cases for which the dose was reported occurred in young children for whom FDA has not proposed a safe and effective dose. Nine of these 11 cases were children younger than 2 years who received a rectal sodium phosphate product, and two were in children younger than 5 years who received an oral product. These children received doses comparable to those recommended on the label for use in adults or older children. Seven adults developed serious adverse events despite taking dosages that did not exceed recommendations on the label; however, all had one or more of the above conditions, potentially increasing their adverse event risk.

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