



## FDA Drug Safety Communication

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

[1-8-2014]

#### **SAFETY ANNOUNCEMENT**

- 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.
  - FDA is continuing to monitor reports of side effects involving Sodium phosphate drugs and will update the public if more information becomes available.

#### **PATIENT AND CAREGIVER RECOMMENDATIONS**

- 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.
  - **The rectal form of these products should never be given to children younger than 2 years.**

#### **HEALTH CARE PROFESSIONAL RECOMMENDATIONS**

- Health care professionals should use caution when recommending an oral dose of these products for children 5 years and younger.

#### **DRUG BENEFITS**

- Sodium phosphate drug products are available over-the-counter and used for the relief of occasional constipation, which occurs when a person has three or fewer bowel movements in a week.

- With constipation, the stool can become hard and dry and can sometimes be difficult or painful to pass, and may lead to more serious problems if untreated.
- Sodium phosphate products include oral solutions taken by mouth and enemas used rectally.

## **SAFETY ISSUE REPORTS**

- FDA has become aware of reports of **severe dehydration and changes in the levels of electrolytes in the blood from taking more than the recommended dose** of OTC sodium phosphate products. This has **resulted in serious harm to organs, such as the kidneys and heart, and death in some cases.**
- 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.
- 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.
  - FAERS includes only reports submitted to FDA so there are likely additional cases about which we are unaware.
  - 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.
  - 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

## **HIGHER RISK INDIVIDUALS**

- **Some individuals may be at higher risk for potential adverse events** when more than the recommended dose of OTC sodium phosphate is taken.
  - 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.

### **PREVIOUS FDA DRUG SAFETY COMMUNICATIONS**

- 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 Patients

### DOSING INSTRUCTIONS

- **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.**

### USAGE WARNINGS

- 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.

### PATIENT ACTIONS

- **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.