

Use Certain Laxatives with Caution

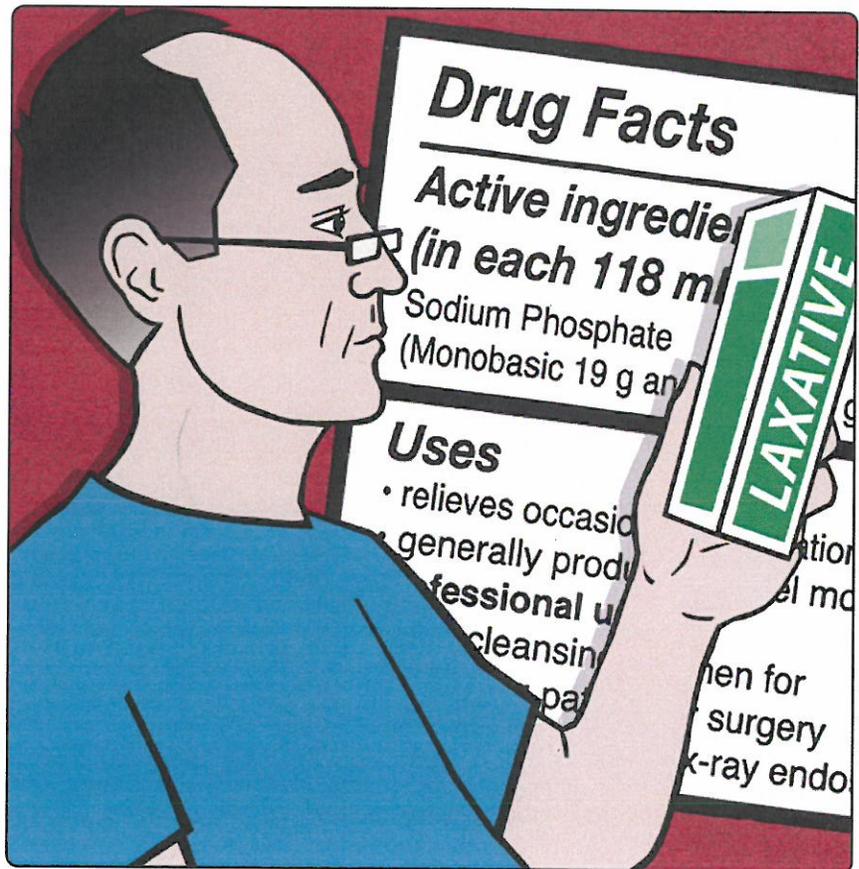
Constipation may not be a subject for polite conversation, but it's a condition that bothers many of us on occasion.

The Food and Drug Administration (FDA) is warning consumers that some of the over-the-counter (OTC) laxatives they may turn to for relief are potentially dangerous if dosing instructions or warnings on the Drug Facts label are not properly followed or when there are certain coexisting health conditions. In fact, there have been dozens of reports of serious side effects, including 13 deaths, associated with the use of sodium phosphate laxatives.

The label of sodium phosphate laxatives states that they should be used as a single dose taken once a day, and the products should not be used for more than three days. Equally important, consumers who do not have a bowel movement after taking an oral or rectal dose should not take another dose of the product.

In addition, labeling instructs adults and children to ask health care professionals before using these products if they have kidney disease, heart problems or dehydration.

FDA is now warning that adults older than 55 and adults and children with certain health conditions should ask a health care professional before using these products because they may be at increased risk for harmful side effects. These new warnings are not currently in the Drug Facts label and apply to both adults and children



- who are taking certain drugs that affect how the kidneys work, such as diuretics or fluid medicines; angiotensin-converting enzyme (ACE) inhibitors used to lower blood pressure; angiotensin receptor blockers (ARBs) used to treat high blood pressure, heart, or kidney failure; and nonsteroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen.
- with inflammation of the colon.

Constipation is marked by infrequent bowel movements or difficulty in passing stools.

Laxatives—taken both orally and rectally—come in different forms, with different ingredients. The sodium phosphate used in some products is in a class of medications called saline laxatives. This class of laxatives helps promote a bowel movement by drawing water into the bowel, which softens the stool and makes it easier to pass.

“The bottom line is that these products are safe for otherwise healthy adults and older children for whom dosing instructions are provided on the Drug Facts label as long as they follow these dosing instructions and don’t take the product more often, or in greater amounts, than the label instructs.”

Laxative products containing sodium phosphates are marketed under the brand name “Fleet” and also as store brands and generic products. All of them are potentially associated with serious side effects, such as dehydration and/or abnormal levels of electrolytes in the blood that can lead to serious complications, such as kidney damage and sometimes death.

Who is Most at Risk?

According to Mona Khurana, M.D., a medical officer in FDA’s Division of Nonprescription Regulation Development and a pediatric nephrologist (a doctor who specializes in children’s kidney diseases), the most serious harm in recent reports occurred after consumers overdosed by taking a single dose that was higher than recommended on the drug label or took more than one dose in a day because they had a poor laxative effect from the first dose.

“The bottom line is that these products are safe for otherwise healthy adults and older children for whom dosing instructions are provided on the Drug Facts label as long as they follow these dosing instructions and don’t take the product more often, or in greater amounts, than the label instructs,” Khurana says.

In recent reviews of harmful side effects reported by consumers and health care professionals, FDA has identified 54 cases of serious side effects associated with the oral or rectal use of OTC sodium phosphate products for the treatment of constipation in adults and children. Thirteen cases were fatal, including one child and 12 adults.

“It is not possible to determine the precise rate of these events as no one knows how many individuals who take these medications may experience side effects,” says Khurana, adding, “Not everybody who develops problems in association with sodium phosphate use reports to the FDA.”

Can these laxatives be used safely in young children?

“Caregivers should not give these products orally to children under age 5 years without first asking a health care professional. Both caregivers and health care professionals should avoid the rectal use of these drug products in children under age 2 years,” Khurana cautions. “These warnings against use in young children are listed on product labeling.”

Warning Signs

Consumers taking these laxatives should watch for warning signs of a bad reaction. For example, a rectal

dose that is retained and does not produce a bowel movement may cause dehydration and/or serious changes in blood electrolyte levels. Symptoms of dehydration include dry mouth, thirst, reduced urine output, and lightheadedness, especially with changes in position. If the rectal dose is retained in the body longer than 30 minutes, a health care professional should be contacted right away.

The symptoms of kidney injury include drowsiness, sluggishness, a decreased amount of urine, or swelling of the ankles, feet and legs. If you experience any of these symptoms after using laxatives containing sodium phosphates, you should seek medical attention immediately.

If you have any concerns about using the products, particularly for use with young children, talk to your health care professional first, Khurana says. [FDA](#)

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