U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

Drug Safety Communications

FDA Drug Safety Communication

FDA recommends separating dosing of potassium-lowering drug sodium polystyrene sulfonate (Kayexalate) from all other oral drugs

This information is an update to the FDA Drug Safety Communication: FDA requires drug interaction studies with potassium-lowering drug Kayexalate (sodium polystyrene sulfonate) issued on October 22, 2015.

Safety Announcement

[09-06-2017] The U.S. Food and Drug Administration (FDA) is recommending that patients avoid taking the potassium-lowering drug sodium polystyrene sulfonate (Kayexalate) at the same time as other medicines taken by mouth. A study found that sodium polystyrene sulfonate binds to many commonly prescribed oral medicines, decreasing the absorption and therefore effectiveness of those oral medicines. To reduce this likelihood, we recommend separating the dosing of sodium polystyrene sulfonate from other orally administered medicines by at least 3 hours. We are updating the sodium polystyrene sulfonate drug labels to include information about this dosing separation.

Sodium polystyrene sulfonate is used to treat hyperkalemia, a serious condition in which the amount of potassium in the blood is too high. It works by binding with potassium in the intestines so it can be removed from the body. Potassium is a mineral that helps the body function properly. Too much potassium in the blood can cause problems with heart rhythm, which in rare cases can be fatal. Sodium polystyrene sulfonate is available as the brand name Kayexalate, as generic brands, and also as non-branded generics.

Patients should take orally administered prescription and over-the-counter (OTC) medicines at least 3 hours before or 3 hours after taking sodium polystyrene sulfonate. Patients should not stop taking their potassium-lowering medicines without talking to their health care professional first. If you have questions or concerns, including about how to take sodium polystyrene sulfonate with other medicines, talk to a pharmacist or other health care professional.

When prescribing sodium polystyrene sulfonate, **health care professionals** should advise patients to separate dosing from other orally administered medicines by at least 3 hours. That time should be increased to 6 hours for patients with gastroparesis or other conditions resulting in delayed emptying of food from the stomach into the small intestine.

A study was conducted in the laboratory, called an *in vitro* study, to evaluate the binding potential for six orally administered medicines commonly taken together with sodium polystyrene sulfonate. These medicines were the blood pressure medicines amlodipine and metoprolol, the antibiotic amoxicillin, the water pill furosemide, the seizure medicine phenytoin,

and the blood-thinner warfarin. The study found significant binding to sodium polystyrene sulfonate occurred with all of these medicines.

Based on our findings, we have concluded that sodium polystyrene sulfonate would also be likely to bind to many other oral medicines, and separating its dosing from other oral medications by 3 hours (6 hours if the patient has gastroparesis) would reduce the risk of binding. The recommended spacing interval is based on the expected amount of time it would take for either sodium polystyrene sulfonate or the other drugs to pass through the stomach. As a result, we have determined that additional drug interaction studies are no longer needed and will be releasing the manufacturer of Kayexalate, Concordia Pharmaceuticals, Inc., from its requirement to conduct further studies. We are also adding the new information about separating the time of administration of orally administered medicines and sodium polystyrene products to the sodium polystyrene sulfonate drug labels.

We urge patients and health care professionals to report side effects involving sodium polystyrene sulfonate products to the FDA MedWatch program, using the information in the "Contact FDA" box at the bottom of the page.

Facts about sodium polystyrene sulfonate (Kayexalate and generics)

- Sodium polystyrene sulfonate products are prescribed to treat hyperkalemia, a condition in which the amount of potassium in the blood is too high. They work by binding with potassium in the intestines so it can be removed from the body.
- Sodium polystyrene sulfonate is available as brand name Kayexalate and as generic brands Kalexate, Kionex, and SPS, as well as non-branded generics.
- Sodium polystyrene sulfonate can be administered as an oral suspension or in an enema.
- Sodium polystyrene sulfonate should not be heated or added to heated foods or liquids as this may decrease the effectiveness of the medicine.
- Common side effects of sodium polystyrene sulfonate include loss of appetite, stomach discomfort, nausea, vomiting, and constipation.
- In 2016, approximately 2.8 million sodium polystyrene sulfonate packages were sold by manufacturers to various U.S. channels of distributions.[1]

Reference

1. QuintilesIMS National Sales Perspectives Database. Year 2016. Extracted August 2017.

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