FDA Safety Alert

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Kayexalate (sodium polystyrene sulfonate): Drug Safety Communication - FDA Requires Drug Interaction Studies

AUDIENCE: Internal Medicine, Nephrology, Cardiology

ISSUE: FDA is requiring the Kayexalate manufacturer to conduct studies to investigate Kayexalate's potential to bind to other medications administered by mouth – drug interactions that could affect how well the other medications work.

The approved labeling for Kayexalate describes its potential to decrease absorption of lithium and thyroxine; however, extensive drug-drug interaction studies with Kayexalate have not been performed. During FDA's review of another potassium-lowering drug, Veltassa (patiromer), we found that Veltassa bound to about half of the medications tested, some of which are commonly used in patients who require potassium-lowering drugs. Such binding could decrease the effects of these medications. The label for Veltassa contains a warning not to take other orally administered medications within 6 hours of taking Veltassa.

Similar to Veltassa, Kayexalate may also bind to other medications administered by mouth. To reduce this potential risk, prescribers and patients should consider separating Kayexalate dosing from other medications taken by mouth by at least 6 hours. This includes both prescription medications, such as antibiotics, blood pressure lowering agents and blood thinners, and those purchased over-the-counter without a prescription, such as antacids and laxatives. Health care professionals should monitor blood levels or clinical response to the other medications when appropriate.

If the studies conducted by the Kayexalate manufacturer, Concordia Pharmaceuticals, confirm significant interactions with other medications, FDA will require all manufacturers of sodium polystyrene sulfonate products to update the drug labels to include information about these drug interactions.

BACKGROUND: Kayexalate (sodium polystyrene sulfonate) and generic brands Kionex and SPS are used to treat hyperkalemia, a serious condition in which the amount of potassium in the blood is too high. They work by binding potassium in the large intestine so it can be removed from the body.

RECOMMENDATION: Prescribers and patients should consider separating Kayexalate dosing from other medications taken by mouth by at least 6 hours. Health care professionals should monitor blood levels

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or clinical response to the other medications when appropriate. Patients should not stop taking their potassium-lowering drugs without talking to their health care professional.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

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