Kayexalate® (sodium polystyrene sulfonate) – Safety update

- On September 6, 2017, the FDA announced that Kayexalate (sodium polystyrene sulfonate) drug labels will be updated to state that the dose should be separated by at least 3 hours from other orally administered drugs.

- Kayexalate is indicated for the treatment of hyperkalemia and 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 also generically available. Kionex® and SPS® are branded generics.

- Patients should take orally administered prescription and over-the-counter medicines ≥ 3 hours before or after taking Kayexalate. Patients should not stop taking their potassium-lowering medicines without talking to their healthcare provider first.

    — Healthcare providers should advise patients to separate Kayexalate dosing from other orally administered medicines by ≥ 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.
    — The recommended spacing interval is based on the expected amount of time it would take for either Kayexalate or the other drugs to pass through the stomach.

- Patients should contact their pharmacist or healthcare provider if they have questions or concerns, including about how to take Kayexalate with other medicines.

- An *in vitro* study demonstrated that Kayexalate binds to many commonly prescribed oral medicines, thereby decreasing their absorption and effectiveness.

- In 2015, the FDA required the manufacturer of Kayexalate, Concordia Pharmaceuticals, to conduct studies to investigate Kayexalate's potential to bind to other oral medications. This safety communication was prompted by the FDA's review of another potassium-lowering drug, Veltassa® (patiromer).

    — The FDA discovered that Veltassa bound to about half of the medications tested, some of which are commonly used in patients who require potassium-lowering drugs.

- Based on the Kayexalate *in vitro* study, the FDA determined that additional drug interaction studies are no longer needed and will be releasing Concordia Pharmaceuticals from its requirement to conduct further studies.

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