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Dear Healthcare Professionals,



DEPARTMENT OF HEALTH
DRUG OFFICE
DRUG REGISTRATION AND
IMPORT/EXPORT CONTROL DIVISION
3/F., Public Health Laboratory Centre,
382 Nam Cheong Street, Kowloon, Hong Kong

7 September 2017

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

Your attention is drawn to the U.S. Food and Drug Administration's (FDA) announcement regarding recommendation on patients avoid taking the potassium-lowering drug sodium polystyrene sulfonate (Kayexalate) at the same time as any 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, FDA recommends separating the dosing of sodium polystyrene sulfonate from other orally administered medicines by at least 3 hours. FDA is 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 in U.S.

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

Please refer to the following website in FDA for details:

<https://www.fda.gov/Drugs/DrugSafety/ucm572484.htm>

In Hong Kong, there are three registered pharmaceutical product containing sodium polystyrene sulfonate, namely Resonium A Powder (HK-42418), PMS-Sodium Polystyrene Sulfonate Powder (HK-44860) and Resinsodio Powder for Oral Suspension 99.75g/100g (HK-64694). So far, the Department of Health (DH) has not received any adverse drug reaction (ADR) cases related to sodium polystyrene sulfonate.

Related news of FDA requiring the Kayexalate manufacturer to conduct studies to investigate Kayexalate's potential to bind to other medications administered by mouth has been released by U.S. FDA, was posted on the Drug Office website on 23 October 2015. Letters to inform local healthcare professionals on the warnings had been issued on the same day. In view of the FDA's recent recommendations on the separate dosing, letters to inform local healthcare professionals of the risk will be issued. The matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Pharmacovigilance Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully



(Joseph LEE)

for Assistant Director (Drug)