Gmail by Google

Richard Zelkowitz <pharmaconcorp@gmail.com>

FDA MedWatch - SGLT2 inhibitors: Drug Safety Communication - FDA Warns Medicines May Result in a Serious Condition of Too Much Acid in the Blood

1 message

FDA MedWatch <fda@service.govdelivery.com>
Reply-To: fda@service.govdelivery.com
To: pharmaconcorp@gmail.com

Fri, May 15, 2015 at 12:52 PM

MEDWATCH The FDA Safety Information and Adverse Event Reporting Program

SGLT2 inhibitors: Drug Safety Communication - FDA Warns Medicines May Result in a Serious Condition of Too Much Acid in the Blood

AUDIENCE: Endocrinology, Family Practice

ISSUE: FDA is warning that the type 2 diabetes medicines canagliflozin, dapagliflozin, and empagliflozin may lead to ketoacidosis, a serious condition where the body produces high levels of blood acids called ketones that may require hospitalization. FDA is continuing to investigate this safety issue and will determine whether changes are needed in the prescribing information for this class of drugs, called sodium-glucose cotransporter-2 (SGLT2) inhibitors.

BACKGROUND: SGLT2 inhibitors are a class of prescription medicines that are FDA-approved for use with diet and exercise to lower blood sugar in adults with type 2 diabetes. When untreated, type 2 diabetes can lead to serious problems, including blindness, nerve and kidney damage, and heart disease. SGLT2 inhibitors lower blood sugar by causing the kidneys to remove sugar from the body through the urine.

These medicines are available as single-ingredient products and also in combination with other diabetes medicines such as metformin.

RECOMMENDATION: Patients should pay close attention for any signs of ketoacidosis and seek medical attention immediately if they experience symptoms such as difficulty breathing, nausea, vomiting, abdominal pain, confusion, and unusual fatigue or sleepiness. Do not stop or change your diabetes medicines without first talking to your prescriber.

Health care professionals should evaluate for the presence of acidosis, including ketoacidosis, in patients experiencing these signs or symptoms; discontinue SGLT2 inhibitors if acidosis is confirmed; and take appropriate measures to correct the acidosis