



Canagliflozin (Invokana, Invokamet) and Dapagliflozin (Farxiga, Xigduo XR): Drug Safety Communication - Strengthened Kidney Warnings

[Posted 06/14/2016]

FDA 發布一則藥物安全警訊，根據通報案例，使用降血糖藥物 SGLT2 (sodium-glucose co-transporter 2) 抑制劑- Canagliflozin 和 Dapagliflozin 會增加急性腎衰竭的風險。為了減少此風險，已經修訂藥品仿單上的警語和增加建議事項。

建議：

醫療人員在開立 Canagliflozin 和 Dapagliflozin 前，應該考慮可能導致患者急性腎衰竭的因素，包括血容量下降、慢性腎功能不全、充血性心臟衰竭和服用其他藥物如利尿劑、降血壓藥物（血管收縮素轉化酶抑制劑（ACEi）和血管收縮素受體阻斷劑（ARBs））和非類固醇消炎藥（NSAIDs）。故使用 Canagliflozin 和 Dapagliflozin 前應該評估病患的腎臟功能，並定期做追蹤。一旦急性腎臟衰竭發生，應該立即停用藥品，並針對腎臟損傷做後續的治療。

病患如果在服用 Canagliflozin 和 Dapagliflozin 後發現有急性腎衰竭的症狀，如排尿量減少、下肢水腫的情形時，應該立即回診，不應該在尚未告知醫師的情況下擅自停止使用藥品，因為自行停藥可能會導致血糖無法控制而造成傷害。

Canagliflozin (Invokana, Invokamet) and Dapagliflozin (Farxiga, Xigduo XR): Drug Safety Communication - Strengthened Kidney Warnings

[Posted 06/14/2016]

AUDIENCE: Endocrinology, Internal Medicine, Nephrology, Pharmacy

ISSUE: FDA has strengthened the existing warning about the risk of acute kidney injury for the type 2 diabetes medicines canagliflozin (Invokana, Invokamet) and dapagliflozin (Farxiga, Xigduo XR). Based on recent reports, we have revised the warnings in the drug labels to include information about acute kidney injury and added recommendations to minimize this risk.

BACKGROUND: Canagliflozin and dapagliflozin are prescription medicines used with diet and exercise to help lower blood sugar in adults with type 2 diabetes. They belong to a class of drugs called sodium-glucose cotransporter-2 (SGLT2) inhibitors. Canagliflozin and dapagliflozin lower blood sugar by causing the kidneys to remove sugar from the body through the urine.

From March 2013, when canagliflozin was approved, to October 2015, FDA received reports of 101 confirmable cases* of acute kidney injury, some requiring hospitalization and dialysis, with canagliflozin or dapagliflozin use (see Drug Safety Communication for the Data Summary). This number includes only

reports submitted to FDA, so there are likely additional cases about which we are unaware.

RECOMMENDATION: Health care professionals should consider factors that may predispose patients to acute kidney injury prior to starting them on canagliflozin or dapagliflozin. These include decreased blood volume; chronic kidney insufficiency; congestive heart failure; and taking other medications such as diuretics, blood pressure medicines called angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs), and nonsteroidal anti-inflammatory drugs (NSAIDs). Assess kidney function prior to starting canagliflozin or dapagliflozin and monitor periodically thereafter. If acute kidney injury occurs, promptly discontinue the drug and treat the kidney impairment.

Patients should seek medical attention immediately if they experience signs and symptoms of acute kidney injury. This is a serious condition in which the kidneys suddenly stop working, causing dangerous levels of wastes to build up in the body. Signs and symptoms of acute kidney injury may include decreased urine or swelling in the legs or feet. Patients should not stop taking their medicine without first talking to their health care professionals. Doing so can lead to uncontrolled blood sugar levels that can be harmful. Read the patient Medication Guide you receive with your canagliflozin or dapagliflozin prescriptions. It explains the benefits and risks associated with the medicine.