Qtern (dapagliflozin and saxagliptin) FDA approved

As of February 28, 2017, the FDA approved a new drug, Qtern, to be given to patients with type 2 diabetes mellitus. More specifically, it is indicated as an adjunct to diet and exercise in patients who have inadequate glycemic control with other agents. It is a combination of a sodium-glucose cotransporter inhibitor and a dipeptidyl peptidse-4 inhibitor. This medication is a tablet with a recommended dose of 10 mg dapagliflozin/ 5 mg saxagliptin taken once in the morning with or without food.

This drug was approved based on results from two clinical trials that showed the combination product administered with metformin was better at reducing the HbA1c of diabetic patients compared to patients taking metformin and just dapagliflozin or saxagliptin alone.

The most common side effects that are associated with this medication are upper respiratory tract infection, urinary tract infection, hypoglycemia, and dyslipidemia. More serious adverse effects include heart failure, hypotension, diabetic ketoacidosis, pancreatitis, and acute kidney injury.

Renal function should be assessed and closely monitored at the start of and while taking this medication. A patient should not be started on Qtern if their eGFR is below 60 mL/min and it should be discontinued if they ever fall below this level. Qtern should also not be given with strong P450 3A4 and 3A5 inhibitors.

Patients should be advised to report any symptoms associated with more serious adverse effects such has heart failure, and hypotension. They should also report if they have had a recent reduction in oral intake or increased fluid loss because of the potential increase in risk for acute kidney injury. Patients should also be advised to skip the dose if they miss one and to resume their dosing schedule as usual with the next dose.

References:

Qtern. Clinical Pharmacology [Internet Database]. Gold Standard, Inc., 2009. Available at: http://www.clinicalpharmacology.com Accessed: March 8th, 2017

Qtern. In: DRUGDEX[®] System [Internet Database]. Greenwood Village, Colo: Thomson Micromedex. Updated periodically. Accessed: March, 8th 2017

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