

Qtern[®] (dapagliflozin/saxagliptin) – New drug approval

- On February 28, 2017, [AstraZeneca announced](#) the FDA approval of [Qtern \(dapagliflozin/saxagliptin\)](#) as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM) who have inadequate control with [Farxiga[®] \(dapagliflozin\)](#) or who are already treated with dapagliflozin and [Onglyza[®] \(saxagliptin\)](#).
- Qtern is not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis, and it should only be used in patients who tolerate 10 mg of dapagliflozin.
- Qtern combines two anti-hyperglycemic agents, dapagliflozin, a sodium-glucose co-transporter 2 (SGLT-2) inhibitor, and saxagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor.
- The efficacy of Qtern was evaluated in a study of 315 T2DM patients. Patients were randomized to saxagliptin or placebo, in combination with dapagliflozin and [metformin](#).
 - Patients treated with add-on saxagliptin therapy had significantly greater reductions in HbA1c from baseline vs. the placebo group (-0.5% vs. -0.2%, respectively; difference between groups in HbA1c: -0.4%, $p < 0.0001$).
 - The proportion of patients achieving HbA1c < 7% at week 24 was 35.3% in the saxagliptin group vs. 23.1% in the placebo group.
- Qtern is contraindicated in patients with a history of a serious hypersensitivity reaction to dapagliflozin or to saxagliptin (eg, anaphylaxis, angioedema or exfoliative skin conditions), and in patients with moderate to severe renal impairment (eGFR < 45 mL/min/1.73 m²), end-stage renal disease, or on dialysis.
- Warnings and precautions of Qtern include pancreatitis, heart failure, hypotension, ketoacidosis, acute kidney injury and impairment in renal function, urosepsis and pyelonephritis, hypoglycemia with concomitant use of insulin or insulin secretagogues, genital mycotic infections, increases in low-density lipoprotein cholesterol, bladder cancer, severe and disabling arthralgia, and bullous pemphigoid.
- There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with Qtern.
- The most common adverse reactions ($\geq 5\%$) reported in patients treated with dapagliflozin 10 mg and saxagliptin 5 mg were upper respiratory tract infection, urinary tract infection, and dyslipidemia.
- The recommended dose of Qtern (dapagliflozin/saxagliptin) is one 10 mg/5 mg tablet taken orally once daily in the morning with or without food.
 - Qtern should not be split or cut.
 - Assessment of renal function should be conducted prior to initiation of Qtern therapy and periodically thereafter.

- AstraZeneca's launch plans for Qtern are pending. Qtern (dapagliflozin/saxagliptin) will be available as 10 mg/5 mg tablets.



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