Qtern (dapagliflozin, saxagliptin)

NEW PRODUCT SLIDESHOW

MPR

Introduction

- **Brand name:** Qtern
- **Generic name:** Dapagliflozin, saxagliptin
- **Pharmacological class:** Sodium-glucose co-transporter 2 (SGLT2) inhibitor + dipeptidyl peptidase-4 (DPP-4) inhibitor
- **Strength and Formulation:** 10mg/5mg; tablets
- **Manufacturer:** AstraZeneca
- **How supplied:** Bottles—30, 90, 500
- **Legal Classification:** Rx

Indications

- Adjunct to diet and exercise to improve glycemic control in adults with **type 2 diabetes** who have inadequate control with dapagliflozin or who are already treated with dapagliflozin and saxagliptin

Limitations of Use

- Not for treating type 1 diabetes or diabetic ketoacidosis
- Only use in patients who tolerate dapagliflozin 10mg

Qtern


QTERN
(dapagliflozin and saxagliptin)
tablets
10 mg/5 mg
Rx only
AstraZeneca

Dosage & Administration

- Swallow whole
- Take 10mg/5mg once daily in the AM
- **Renal impairment:** do not initiate if eGFR <60mL/min/1.73m^2; discontinue if eGFR falls persistently <60mL/min/1.73m^2

Contraindications

- Moderate-to-severe renal impairment (eGFR <45mL/min/1.73m^2), ESRD, or dialysis

Considerations for Special Populations

- **Pregnancy:** Avoid during 2nd and 3rd trimesters
- **Nursing mothers:** Not recommended
- **Pediatric:** <18yrs: not established
- **Renal impairment:** See Dosing and Contraindications
- **Hepatic impairment:** Safety, efficacy not established in severe impairment

Warnings/Precautions

- Correct volume depletion and assess for volume contraction before initiating
- Monitor for symptomatic hypotension after starting therapy (esp. elderly, renal impairment, or on loop diuretics)
- Assess for ketoacidosis in presence of signs/symptoms of metabolic acidosis, regardless of blood glucose levels; discontinue if suspected, evaluate and treat; consider risk factors before initiation (eg, pancreatic insulin deficiency, caloric restriction, alcohol abuse)

Warnings/Precautions

- Evaluate renal function prior to starting and monitor periodically thereafter; more frequently if eGFR <60mL/min/1.73m^2
- Risk of acute kidney injury in hypovolemia, chronic renal insufficiency, CHF, and concomitant drugs (eg, diuretics, ACEIs, ARBs, NSAIDs)
- Consider temporarily discontinuing in reduced oral intake or fluid losses; monitor for acute kidney injury; discontinue and treat if occurs

Warnings/Precautions

- Consider risks/benefits in patients with known risk factors for heart failure; monitor for signs/symptoms; evaluate and consider discontinuing if develops
- Monitor for signs/symptoms of pancreatitis, serious hypersensitivity reactions, severe joint pain, or bullous pemphigoid; discontinue if suspected or occurs
- Monitor for genital mycotic infections, UTIs, increases in LDL-C; treat as appropriate

Warnings/Precautions

- Active bladder cancer: not recommended
- Prior history of bladder cancer: consider benefits/risks
- History of angioedema to other DPP-4 inhibitors

Interactions

- **Concomitant strong CYP3A4/5 inhibitors** (eg, ketoconazole, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, ritonavir, saquinavir, telithromycin): not recommended

- Consider a lower dose of concomitant insulin or insulin secretagogue (eg, sulfonylurea) to reduce risk of hypoglycemia

Interactions

- Greater potential for volume depletion with concomitant **diuretics**
- May result in false (+) urine glucose tests or unreliable measurements of 1,5-AG assay; use alternative methods to monitor glycemic control

Adverse Reactions

- Upper RTIs
- UTIs
- Dyslipidemia
- Headache
- Diarrhea
- Back pain
- Arthralgia
- Increases in LDL-C
- Genital mycotic infections (esp. females)
- Hypersensitivity reactions
- Pancreatitis
- Heart failure
- Hypotension
- Ketoacidosis
- Renal impairment
- Urosepsis
- Pyelonephritis
- Bladder cancer
- Possible severe and disabling arthralgia
- Bullous pemphigoid

Mechanism of Action

- **Dapagliflozin**, an inhibitor of SGLT-2, reduces reabsorption of filtered glucose and lowers the renal threshold for glucose, and thereby increases urinary glucose excretion

- **Saxagliptin** is a competitive DPP-4 inhibitor that slows the inactivation of the incretin hormones, thereby increasing their bloodstream concentrations and reducing fasting and postprandial glucose concentrations in a glucose-dependent manner

Clinical Studies

- A 24-week randomized, double-blind, placebo-controlled trial (N=315) evaluated the safety and efficacy of saxagliptin added to dapagliflozin and metformin in patients with a baseline HbA1c ≥7–≤10.5%

- Patients treated with add-on saxagliptin showed statistically significant greater reductions in HbA1c from baseline vs placebo (**−0.5** vs **−0.2**; difference −0.4, [95% CI: −0.5, −0.2]; *P*<0.0001)

Clinical Studies

- The proportion of patients achieving HbA1c <7% at Week 24 was **35.3%** in the saxagliptin treated group vs **23.1%** in the placebo group

New Product Monograph

- For more information view the product monograph available at:

  https://www.empr.com/qtern/drug/34774/