

Brand Name: Qtern

Generic: dapagliflozin and saxagliptin

Type: small molecule

Year Accepted/Phase: 2017

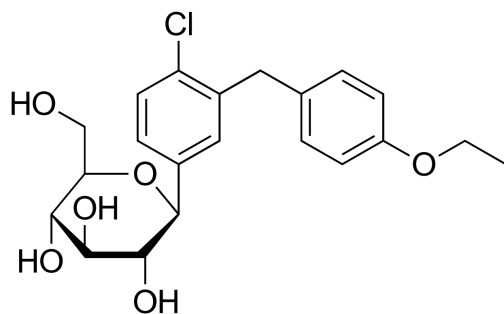
Mechanism:

Dapagliflozin: Inhibits SGLT2 in the proximal renal tubules, reducing glucose reabsorption and increasing urinary glucose excretion, thereby lowering blood glucose levels.

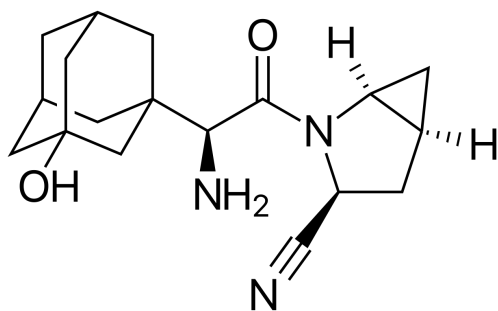
Saxagliptin: Inhibits DPP-4, preventing the degradation of incretin hormones, which increases insulin release and decreases glucagon secretion in a glucose-dependent manner.

Chemical Structure:

dapagliflozin



saxagliptin



Indication:

Qtern is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Clinical trials:

Phase III Trials for Combination Therapy

Purpose: Assess the efficacy and safety of the combination of dapagliflozin and saxagliptin in patients with type 2 diabetes inadequately controlled on metformin alone.

Dates: Conducted between 2013 and 2015.

Results: The phase III clinical trials demonstrated that the combination of dapagliflozin and saxagliptin significantly improved glycemic control, as indicated by reductions in HbA1c, compared to placebo or either drug alone. The combination therapy also showed a favorable safety profile, with the most common adverse events being urinary tract infections and hypoglycemia.

Impact: These trials provided strong evidence supporting the efficacy and safety of the combination therapy, leading to its approval.

DURATION-8 Trial (Phase III)

Pubmed: <https://pubmed.ncbi.nlm.nih.gov/27651331/>

Purpose: Evaluate the efficacy and safety of the fixed-dose combination of dapagliflozin and saxagliptin in patients with type 2 diabetes inadequately controlled with metformin.

Dates: Conducted from 2013 to 2015.

Results: The DURATION-8 trial found that the fixed-dose combination significantly reduced HbA1c levels, fasting plasma glucose, and body weight compared to either drug alone. The combination therapy also had a good safety profile, with no new safety concerns identified.

Impact: This trial reinforced the benefits of the fixed-dose combination for better glycemic control and weight management in patients with type 2 diabetes.