

Qtern® (dapagliflozin/saxagliptin) – Expanded indication

- On May 2, 2019, the FDA approved <u>Qtern (dapagliflozin/saxagliptin)</u> as an adjunct to diet and exercise to improve glycemic control in adults with T2DM.
 - Previously, Qtern was indicated for use in adults with T2DM who have inadequate control
 with dapagliflozin or who are already treated with dapagliflozin and saxagliptin.
 - Qtern is not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.
- Dapagliflozin and saxagliptin in combination with metformin has been studied in adult patients with T2DM inadequately controlled on metformin. Treatment with dapagliflozin and saxagliptin and metformin (combination or add-on therapy) at all doses produced statistically significant improvements in HbA1c compared to the active comparator or placebo study arms in combination with metformin.
- For patients not already taking dapagliflozin, the recommended starting dose of Qtern is a 5 mg dapagliflozin/5 mg saxagliptin tablet taken orally once daily in the morning with or without food.
 - In patients tolerating 5 mg dapagliflozin and 5 mg saxagliptin once daily who require additional glycemic control, the Qtern dose can be increased to 10 mg dapagliflozin/5 mg saxagliptin tablet once daily.
 - Qtern should be swallowed whole.



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