

Qternmet[®] XR (dapagliflozin/saxagliptin/metformin) – New drug approval

- On May 3, 2019, [AstraZeneca announced](#) the [FDA approval](#) of [Qternmet XR \(dapagliflozin/saxagliptin/metformin\)](#) extended release tablets as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).
 - Qternmet XR is not indicated for the treatment of type 1 diabetes mellitus or diabetic ketoacidosis.
 - Qternmet XR initiation is intended only for patients currently taking metformin.
- Qternmet XR is a once-daily, oral drug comprised of the sodium-glucose cotransporter-2 inhibitor dapagliflozin, the dipeptidyl peptidase-4 inhibitor saxagliptin, and metformin.
- Dapagliflozin and saxagliptin plus 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.
- Qternmet XR contains a boxed warning for lactic acidosis.
- Qternmet XR is contraindicated in patients with a history of a serious hypersensitivity reaction to dapagliflozin, saxagliptin, or metformin, including anaphylaxis, angioedema, or exfoliative skin conditions; patients with moderate to severe renal impairment; and in acute or chronic metabolic acidosis, including diabetic ketoacidosis, with or without coma.
- Additional warnings and precautions of Qternmet XR 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, necrotizing fasciitis of the perineum, vitamin B12 concentrations, 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 Qternmet XR.
- The most common adverse reactions ($\geq 5\%$) reported with Qternmet XR use were upper respiratory tract infection, urinary tract infection, and dyslipidemia.
- The starting dose of Qternmet XR is based on the patient's current regimen, effectiveness, and tolerability.
 - Renal function should be assessed before initiating Qternmet XR and periodically thereafter.
 - Volume depletion should be corrected prior to initiating Qternmet XR.
 - For patients not currently taking dapagliflozin, the recommended starting total daily dose of Qternmet XR is 5 mg dapagliflozin/5 mg saxagliptin/1000 mg or 2000 mg metformin hydrochloride extended-release once daily.
 - The maximum recommended daily dose is 10 mg dapagliflozin, 5 mg saxagliptin, and 2000 mg metformin extended-release.
 - Qternmet XR is taken orally, once daily in the morning with food.

- AstraZeneca's launch plans for Qternmet XR are pending. Qternmet XR (dapagliflozin/saxagliptin/metformin extended release) will be available as 2.5 mg/2.5 mg/1000 mg, 5 mg/2.5 mg/1000 mg, 5 mg/5 mg/1000 mg, and 10 mg/5 mg/1000 mg tablets.



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