

New Drug Approvals

Generic Name (Trade Name—Company)

December 28, 2017

Ertugliflozin

(Steglatro—Pfizer, Merck)

New SGLT2 inhibitor approved for glycemic control in adults with type 2 diabetes

Uses/Notes

[FDA has approved](#) ertugliflozin tablets, an oral sodium-glucose cotransporter 2 (SGLT2) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

Approval was based on clinical trials of ertugliflozin as monotherapy and in combination with metformin and/or sitagliptin, as well as with insulin and a sulfonylurea, in adults with type 2 diabetes and moderate renal impairment. Treatment resulted in significant A1C reductions when used alone or in combination with sitagliptin.

Ertugliflozin is not recommended in patients with type 1 diabetes or for treatment of diabetic ketoacidosis. It is contraindicated in patients with severe renal impairment, end-stage renal disease, or who are on dialysis, or with patients who have a history of a serious hypersensitivity reaction to ertugliflozin.

The agent causes intravascular volume contraction. Symptomatic hypotension may occur after initiation, particularly in patients with impaired renal function (estimated glomerular filtration rate [eGFR] less than 60 mL/min/1.73 m²), older adult patients (>65 y), patients with low systolic blood pressure, or patients on diuretics. Before starting ertugliflozin, volume status should be assessed and corrected if indicated. Monitor for signs and symptoms after initiating therapy.

The most common adverse reactions associated with the agent (incidence >5%) were female genital mycotic infections.

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