

Jardiance[®] (empagliflozin), Synjardy[®] (empagliflozin/metformin) – Expanded indication

- On June 20, 2023, the [FDA announced](#) the approval of Boehringer Ingelheim and [Eli Lilly's Jardiance \(empagliflozin\)](#) and [Synjardy \(empagliflozin/metformin\)](#), as an adjunct to diet and exercise to improve glycemic control in **adults and pediatric patients aged 10 years and older** with type 2 diabetes mellitus (T2DM).
 - Jardiance and Synjardy were previously approved for this indication in adults only.
 - Jardiance and Synjardy are not recommended in patients with type 1 diabetes mellitus. It may increase the risk of diabetic ketoacidosis in these patients.
- Jardiance is also approved:
 - To reduce the risk of cardiovascular (CV) death and hospitalization for heart failure in adults with heart failure
 - To reduce the risk of CV death in adults with T2DM and established CV disease.
- The approval of Jardiance for the expanded indication was based on DINAMO, a randomized, double-blind, placebo-controlled study in 157 pediatric patients aged 10 to 17 years with inadequately controlled T2DM. Patients were randomized to 3 treatment arms: Jardiance, a dipeptidyl peptidase-4 (DPP-4) inhibitor, or placebo, over 26 weeks.
 - At week 26, treatment with Jardiance was superior in reducing HbA1c from baseline vs. placebo. The change from baseline in HbA1c was -0.2 with Jardiance vs. 0.7 with placebo (treatment difference 0.8, 95% CI: -1.5, -0.2; p = 0.0116).
- Synjardy carries a boxed warning for lactic acidosis.
- The recommended dose of Jardiance for treatment of T2DM in pediatric patients is 10 mg orally once daily in the morning, taken with or without food.
- In pediatric patients aged 10 years and older with T2DM, the dosage of Synjardy should be individualized based on the patient's current regimen. The effectiveness and tolerability should be monitored, and dosage adjusted as appropriate, not to exceed the maximum total daily dosage of empagliflozin 25 mg and metformin HCl 2,000 mg.
- Refer to the Jardiance and Synjardy drug labels for dosing for their other uses.