

Invokana[®] (canagliflozin), Invokamet/Invokamet[®] XR (canagliflozin/metformin) – Expanded indication

- On December 18, 2024, the <u>FDA approved</u> Janssen's <u>Invokana (canagliflozin)</u> and <u>Invokamet/Invokamet XR (canagliflozin/metformin)</u>, 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.
 - Invokana and Invokamet/Invokamet XR were previously approved for this indication in adults only. This update expands the approval to include pediatric patients aged 10 years and older.
- Canagliflozin is also approved:
 - To reduce the risk of major adverse cardiovascular events (cardiovascular death, nonfatal myocardial infarction and nonfatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease
 - To reduce the risk of end-stage kidney disease, doubling of serum creatinine, cardiovascular death, and hospitalization for heart failure in adults with type 2 diabetes mellitus and diabetic nephropathy with albuminuria greater than 300 mg/day.
- The approval of these products for the expanded indication was based on a double-blind, placebo-controlled study in 171 pediatric patients aged 10 to 17 years with inadequately controlled type 2 diabetes mellitus. Patients were randomized to Invokana or placebo. The primary endpoint was the change in HbA_{1c} at week 26.
 - At week 26, the change from baseline in HbA_{1c} was -0.38 with Invokana vs. +0.34 with placebo (difference -0.73, 95% CI: -1.26, -0.19; p = 0.008).
- Invokamet/Invokamet XR carry a boxed warning for lactic acidosis.
- The recommended starting dosage of Invokana for glycemic control is 100 mg orally once daily, taken before the first meal of the day. For additional glycemic control, the dose may be increased to the maximum recommended dosage of 300 mg once daily.
 - Refer to the Invokamet/Invokamet XR drug label for its dosing and to the Invokana drug label for its other indications.



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