

Zituvimet (sitagliptin/metformin) – New drug approval

- On November 3, 2023, the [FDA approved](#) Zydus Pharmaceuticals' [Zituvimet \(sitagliptin/metformin\)](#), as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM).
 - Zituvimet is not recommended in patients with type 1 diabetes mellitus.
 - Zituvimet has not been studied in patients with a history of pancreatitis. It is unknown whether patients with a history of pancreatitis are at increased risk for the development of pancreatitis while using Zituvimet.
- Zituvimet contains sitagliptin, a dipeptidyl peptidase-4 (DPP-4) inhibitor, and metformin hydrochloride, a biguanide. This combination is also approved under the brand name [Janumet[®]](#) for the same indication as Zituvimet.
- Zituvimet carries a boxed warning for lactic acidosis.
- Zituvimet is contraindicated in patients with:
 - Severe renal impairment (estimated glomerular filtration rate [eGFR] below 30 mL/min/1.73 m²)
 - Acute or chronic metabolic acidosis, including diabetic ketoacidosis
 - A history of a serious hypersensitivity reaction to sitagliptin, metformin, or any of the excipients in Zituvimet.
- Additional warnings and precautions for Zituvimet include pancreatitis; heart failure; acute renal failure; vitamin B12 deficiency; hypoglycemia with concomitant use with insulin or insulin secretagogues; hypersensitivity reactions; severe and disabling arthralgia; and bullous pemphigoid.
- The most common adverse reactions ($\geq 5\%$) with patients simultaneously started on sitagliptin and metformin and more commonly than in patients treated with placebo were diarrhea, upper respiratory tract infection, and headache.
- The recommended starting dose of Zituvimet in patients not currently treated with metformin is 50 mg sitagliptin and 500 mg metformin twice daily, with gradual dose escalation recommended to reduce gastrointestinal side effects associated with metformin.
- The starting dose in patients already treated with metformin should provide sitagliptin dosed as 50 mg twice daily (100 mg total daily dose) and the dose of metformin already being taken. For patients taking metformin 850 mg twice daily, the recommended starting dose of Zituvimet is 50 mg sitagliptin and 1,000 mg metformin twice daily.
- The maximum recommended daily dose of Zituvimet is 100 mg of sitagliptin and 2,000 mg of metformin.
- Zydus Pharmaceuticals' launch plans for Zituvimet are pending. Zituvimet will be available as tablets containing:

- Sitagliptin 50 mg and metformin 500 mg
- Sitagliptin 50 mg and metformin 1,000 mg



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