



Before prescribing JANUVIA, please read the Prescribing Information.

Total daily dose  **100 mg**

Tablet may not print at actual size or color.



Once-Daily Dosing for Proven 24-Hour Glycemic Control

Indications and usage

JANUVIA is a dipeptidyl peptidase-4 (DPP-4) inhibitor indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Important limitations of use:

- JANUVIA should not be used in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.
- JANUVIA 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 of developing pancreatitis while taking JANUVIA.

Dosage and administration

The recommended dose of JANUVIA is 100 mg once daily. JANUVIA can be taken with or without food.

A dosage adjustment is recommended for patients with moderate or severe renal insufficiency or end-stage renal disease. Assessment of renal function is recommended before initiating therapy with JANUVIA and periodically thereafter.

Dosage adjustments in patients with moderate, severe, or end-stage renal disease (ESRD)



50 mg once daily
Moderate

CrCl ≥ 30 to < 50 mL/min
~Serum Cr levels (mg/dL)
Men: $> 1.7 - \leq 3.0$
Women: $> 1.5 - \leq 2.5$



25 mg once daily
Severe and ESRD

CrCl < 30 mL/min
~Serum Cr levels (mg/dL)
Men: > 3.0
Women: > 2.5
or on dialysis

Tablets may not print at actual size or color.

Selected Important Risk Information

JANUVIA is contraindicated in patients with a history of a serious hypersensitivity reaction to sitagliptin, such as anaphylaxis or angioedema.

There have been postmarketing reports of acute pancreatitis, including fatal and nonfatal hemorrhagic or necrotizing pancreatitis, in patients taking JANUVIA. After initiating JANUVIA, observe patients carefully for signs and symptoms of pancreatitis. If pancreatitis is suspected, promptly discontinue JANUVIA and initiate appropriate management. It is unknown whether patients with a history of pancreatitis are at increased risk of developing pancreatitis while taking JANUVIA.

Selected Important Risk Information (*cont*)

When JANUVIA® (sitagliptin) tablets were used in combination with a sulfonylurea or insulin, medications known to cause hypoglycemia, the incidence of hypoglycemia was increased over that of placebo. Therefore, a lower dose of sulfonylurea or insulin may be required to reduce the risk of hypoglycemia.

There have been postmarketing reports of serious hypersensitivity reactions in patients treated with JANUVIA, such as anaphylaxis, angioedema, and exfoliative skin conditions including Stevens-Johnson syndrome. Because these reactions are reported voluntarily from a population of uncertain size, it is generally not possible to reliably estimate their frequency or establish a causal relationship to drug exposure. Onset of these reactions occurred within the first 3 months after initiation of treatment with JANUVIA, with some reports occurring after the first dose. If a hypersensitivity reaction is suspected, discontinue JANUVIA, assess for other potential causes for the event, and institute alternative treatment for diabetes.

In clinical studies, the adverse reactions reported, regardless of investigator assessment of causality, in $\geq 5\%$ of patients treated with JANUVIA as monotherapy and in combination therapy and more commonly than in patients treated with placebo, were upper respiratory tract infection, nasopharyngitis, and headache.

To report SUSPECTED ADVERSE REACTIONS, contact Merck at 1-877-888-4231 or the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Before prescribing JANUVIA, please read the Prescribing Information, available at Januvia.com/hcp.



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