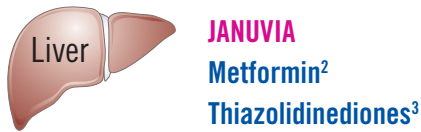


# Selected oral agents for type 2 diabetes

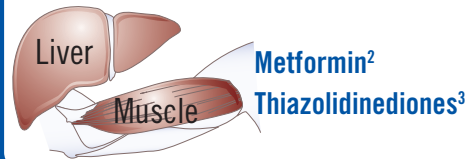
## Insufficient insulin release



## Hepatic glucose overproduction



## Insulin resistance



## Role of JANUVIA

- DPP-4 rapidly degrades incretins
- JANUVIA increases and prolongs active incretin levels
- Incretins stimulate insulin release and suppress glucagon secretion in a glucose-dependent manner

DPP-4=dipeptidyl peptidase-4.

**JANUVIA is indicated** as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

**JANUVIA should not be used** in patients with type 1 diabetes or for the treatment of diabetic ketoacidosis.

**JANUVIA has not been studied** in combination with insulin.

**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.

## 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.

**A dosage adjustment** is recommended in patients with moderate or severe renal insufficiency or with end-stage renal disease requiring hemodialysis or peritoneal dialysis.

**As is typical** with other antihyperglycemic agents used in combination with a sulfonyleurea, when JANUVIA was used in combination with a sulfonyleurea, a class of medications known to cause hypoglycemia, the incidence of hypoglycemia was increased over that of placebo. Therefore, a lower dose of sulfonyleurea 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.

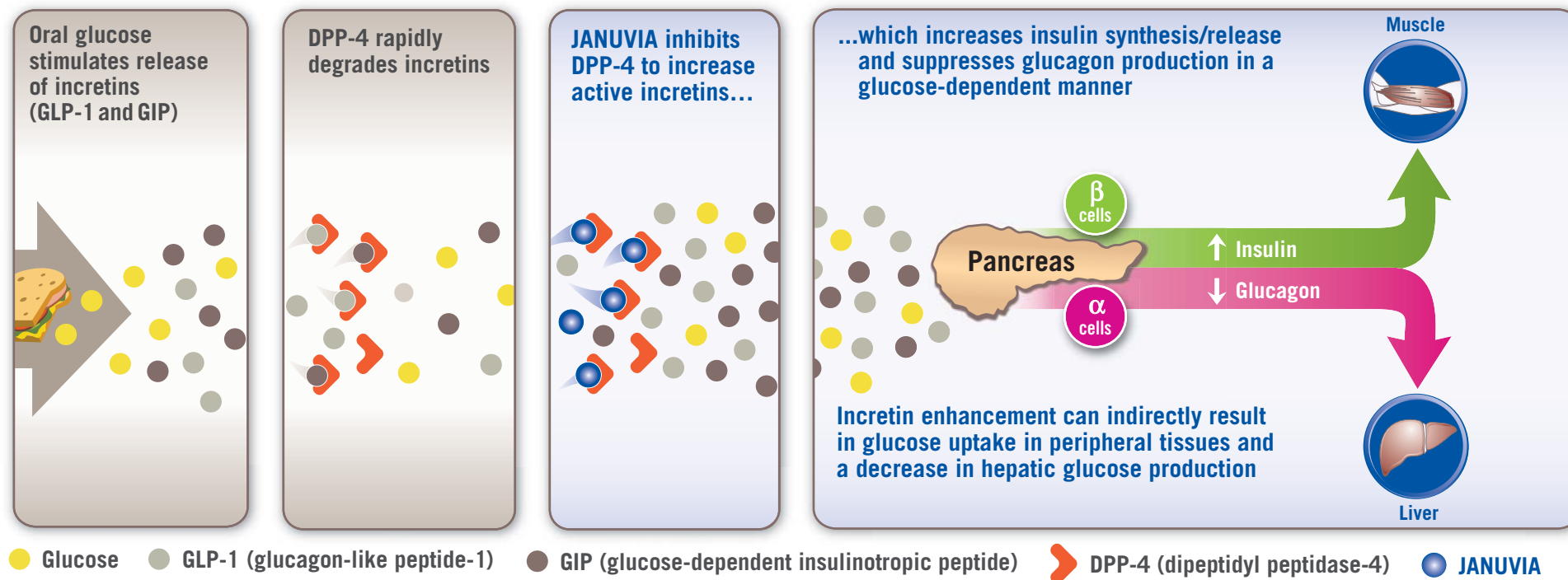
If a hypersensitivity reaction is suspected, discontinue JANUVIA, assess for other potential causes for the event, and institute alternative treatment for diabetes.



*(Selected Important Risk Information continues on page 2.)*

# JANUVIA targets 2 physiologic glucose-lowering actions with a single oral agent

## Glucose-dependent mechanism targets 2 key defects: insufficient insulin release and hepatic glucose overproduction



### Selected Important Risk Information (cont)

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.

**Before prescribing JANUVIA, please read the accompanying Prescribing Information.**

For additional copies of the Prescribing Information, call 1-800-672-6372, visit [Januvia.com/hcp](http://Januvia.com/hcp), or contact your Merck representative.

**References:** 1. Glucotrol [package insert]. New York, NY: Pfizer Inc; 2006. 2. Glucophage [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; 2009. 3. Actos [package insert]. Osaka, Japan: Takeda Pharmaceutical Company Limited; 2007.



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