Rx UPDATE
September 2009

Acute Pancreatitis Reported in Patients Receiving Januvia® (sitagliptin) and Janumet® (sitagliptin/metformin)

On September 25, 2009, the U.S. Food and Drug Administration (FDA) announced it was revising the prescribing information for Januvia (sitagliptin) and Janumet (sitagliptin/metformin) to include information on 88 cases of reported pancreatitis. Sitagliptin is an anti-diabetic drug and is a member of the dipeptidyl peptidase-4 (DPP-4) inhibitor class. It is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

The 88 cases of acute pancreatitis were reported to the FDA between October 16, 2006 and February 9, 2009. Of the 88 cases, two cases of hemorrhagic or necrotizing pancreatitis required an extended stay in the hospital with medical management in the intensive care unit. The most commonly reported adverse events were abdominal pain, nausea and vomiting. The FDA analysis also found that 21 percent of the reported cases of pancreatitis occurred within 30 days of starting sitagliptin or sitagliptin/metformin, and 53 percent of the cases resolved once sitagliptin was discontinued. Additionally, 51 percent of the cases were associated with at least one other risk factor for developing pancreatitis, such as diabetes, obesity, high cholesterol and/or high triglycerides.

The FDA is working with the manufacturer of sitagliptin and sitagliptin/metformin to update the prescribing information to include:

- Information regarding post-marketing reports of acute pancreatitis, including the severe forms, hemorrhagic or necrotizing pancreatitis.
- Recommending that health care professionals monitor patients carefully for the development of pancreatitis after initiation or dose increases of sitagliptin or sitagliptin/metformin, and to discontinue sitagliptin or sitagliptin/metformin if pancreatitis is suspected while using these products.
- Information noting that these medications have not been studied in patients with a history of pancreatitis. Therefore, it is not known whether these patients are at an increased risk for developing pancreatitis while using sitagliptin or sitagliptin/metformin. Sitagliptin or sitagliptin/metformin should be used with caution and with appropriate monitoring in patients with a history of pancreatitis.

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Acute Pancreatitis Reported in Patients Receiving Januvia® (sitagliptin) and Janumet® (sitagliptin/metformin) (continued)

Please note that the FDA-required changes in prescribing information do not currently apply to the other member of this drug class, Onglyza™ (saxagliptin).

As part of our pharmacy benefit management services, Catalyst Rx partners with clients, members, physicians, and pharmacies to provide updates regarding medication safety issues, industry news and changes to product availability. At this time, Catalyst Rx recommends no change in the formulary status of Januvia or Janumet. Catalyst Rx will continue to carefully monitor the situation and provide updates as appropriate. If you have questions, please call the Catalyst Rx Clinical Department at 702-869-4600.

Reference:

http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm183764.htm