Rx UPDATE

November 2009

Altered Kidney Function in Patients using Byetta® (exenatide)

On November 2, 2009, the U.S. Food and Drug Administration (FDA) announced it was revising the prescribing information for Byetta® (exenatide) injection to include information on 78 cases of altered kidney function. Exenatide is an injectable anti-diabetic drug which is currently the only member of the glucagon-like peptide-1 (GLP-1) agonist class. Exenatide is FDA-indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. Exenatide enhances glucose-dependent insulin secretion by the pancreatic beta-cell, suppresses inappropriately elevated glucagon secretion and slows gastric emptying.

From April 2005 through October 2008, the FDA received reports of 62 cases of acute renal failure and 16 cases of renal insufficiency (a total of 78 cases) in patients using exenatide. Reported cases of altered kidney function represent a very small percentage of the total number of patients who have used Byetta. Some cases occurred in patients with pre-existing kidney disease or in patients with one or more risk factors for developing kidney problems. Ninety-five percent (95%) of the patients had at least one contributory risk factor for altered kidney function, including cardiac insufficiency, hypertension, pancreatitis, rhabdomyolysis and urinary tract infection as well as concomitant medications such as anti-retroviral agents, diuretics and non-steroidal anti-inflammatory drugs. These factors could independently increase the risk for developing altered kidney function. Additionally, 54 percent of these patients reported symptoms such as diarrhea and/or vomiting, which are are the most commonly reported side effects associated with the use of exenatide and are also known as risk factors for altered kidney function.

Fifty percent (50%) of patients reported improved signs and symptoms after discontinuation of exenatide. Hospitalization was required in 91 percent of patients and there were four deaths in the cases reviewed by the FDA. Eighteen of the 78 patients required dialysis and two patients required kidney transplantation after initiation of exenatide.

Updates to the prescribing information include:

- Information regarding the post-marketing reports of acute renal failure and insufficiency, highlighting that exenatide should not be used in patients with severe renal impairment (creatinine clearance <30 ml/min) or end-stage renal disease.
- Caution should be applied when initiating or increasing doses of exenatide from 5mcg to 10mcg in patients with moderate renal impairment (creatinine clearance 30 to 50 ml/min).
- Recommendations that healthcare professionals monitor patients carefully for the development of kidney dysfunction and evaluate the continued need for exenatide if kidney dysfunction is suspected while using exenatide.

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Altered Kidney Function in Patients using Byetta® (exenatide)

If you are currently using Byetta:

- Do not discontinue use or change your prescribed medication without first talking to your physician.
- Pay close attention for any signs or symptoms of altered kidney function, such as changes in urination (i.e. color, frequency, amount), unexplained swelling in your extremities, changes in blood pressure, lethargy, changes in appetite or digestion, or dull ache in your mid to lower back.
- Contact your physician if you experience nausea, vomiting, diarrhea or dehydration while using Byetta, as these symptoms may increase the likelihood of developing altered kidney function.

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 Byetta. 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.

References:

http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/DrugSafetyInformationforHeathcareProfessionals/ucm188656.htm

http://www.amylin.com/products/byetta.htm

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