

Drugs

Exenatide (marketed as Byetta) Information

[11/02/2009] FDA has approved revisions to the drug label for Byetta (exenatide) to include information on post-marketing reports of altered kidney function, including acute renal failure and insufficiency.

Byetta, an incretin-mimetic, is approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

From April 2005 through October 2008, FDA received 78 cases of altered kidney function (62 cases of acute renal failure and 16 cases of renal insufficiency), in patients using Byetta. Some cases occurred in patients with pre-existing kidney disease or in patients with one or more risk factors for developing kidney problems. From April 2005 through September 2008, more than 6.6 million prescriptions¹ for Byetta were dispensed. Therefore, the 78 reported cases of altered renal function represent a small percentage of the total number of patients who have used the drug.

Some of the 78 patients reported nausea, vomiting, and diarrhea--the most common side effects associated with Byetta in clinical trials. These side effects may have contributed to the development of altered kidney function in the reported cases.

The revisions to the drug label allow healthcare professionals to better weigh the known benefits of Byetta with the potential risks that exist for certain patients. Changes include:

- Information regarding post-market reports of acute renal failure and insufficiency, highlighting that Byetta should not be used in patients with severe renal impairment (creatinine clearance <30 ml/min) or end-stage renal disease.
- Recommendations to healthcare professionals that caution should be applied when initiating or increasing doses of Byetta from 5 mcg to 10 mcg 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 Byetta if kidney dysfunction is suspected while using the product.
- Information about kidney dysfunction in the patient Medication Guide to help patients understand the benefits and potential risks associated with Byetta.

This information reflects FDA's current analysis of data available to FDA concerning this drug. FDA is not advising practitioners to discontinue prescribing

the product. FDA intends to update this sheet when additional information or analyses become available.

Adverse reactions or quality problems experienced with the use of this Product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax, using the contact information at the bottom of this sheet.

Related Information

- [Information for Healthcare Professionals: Reports of Altered Kidney Function in patients using Exenatide \(Marketed as Byetta\)](#)
11/2/2009
- [Information for Healthcare Professionals: Exenatide \(marketed as Byetta\) - 8/2008 Update](#)
8/18/2008

Labeling and Regulatory History from Drugs@FDA

- [Exenatide \(marketed as Byetta\) Approval and Labeling Information](#)

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