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Information for Healthcare Professionals Exenatide (marketed as Byetta)

Update 8/18/2008: Since issuing [Information for Healthcare Professionals](#) in October 2007, FDA has received reports of 6 cases of hemorrhagic or necrotizing pancreatitis in patients taking Byetta. Byetta is a medicine given by subcutaneous injection to help treat adults with type 2 diabetes. Of the 6 cases of hemorrhagic or necrotizing pancreatitis, all patients required hospitalization, two patients died and four patients were recovering at time of reporting. Byetta was discontinued in all 6 cases.

Byetta and other potentially suspect drugs should be promptly discontinued if pancreatitis is suspected. There are no known patient characteristics which determine when pancreatitis associated with Byetta will be complicated by the hemorrhagic or necrotizing forms of this condition. If pancreatitis is confirmed, initiate appropriate treatment and carefully monitor the patient until recovery. Byetta should not be restarted. Consider antidiabetic therapies other than Byetta in patients with a history of pancreatitis.

FDA is working with the maker of Byetta, Amylin Pharmaceuticals, Inc., to add stronger and more prominent warnings in the product label about the risk of acute hemorrhagic or necrotizing pancreatitis.

The prior FDA ALERT on the topic of acute pancreatitis in patients taking Byetta is shown below.

FDA ALERT [10/2007]: FDA has reviewed 30 postmarketing reports of acute pancreatitis in patients taking Byetta, a drug used to treat adults with type 2 diabetes. An association between Byetta and acute pancreatitis is suspected in some of these cases.

Healthcare professionals should instruct patients taking Byetta to seek prompt medical care if they experience unexplained persistent severe abdominal pain which may or may not be accompanied by vomiting. If pancreatitis is suspected, Byetta should be discontinued. If pancreatitis is confirmed, Byetta should not be restarted unless an alternative etiology is identified.

FDA has asked and the maker of Byetta, Amylin Pharmaceuticals, Inc. has agreed to include information about acute pancreatitis in the PRECAUTIONS section of the product label.

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.

To report any unexpected adverse or serious events associated with the use of this drug, please contact the FDA MedWatch program and complete a form on line at <http://www.fda.gov/medwatch/report/hcp.htm> or report by fax to 1-800-FDA-0178, by mail using the postage-paid address form provided on line, or by telephone to 1-800-FDA-1088.

The Byetta full prescribing information will include new information in the PRECAUTIONS section about the potential for acute pancreatitis in patients taking Byetta.

Recommendations and Considerations

- **Healthcare providers should be alert to the signs and symptoms of acute pancreatitis.** Symptoms include persistent severe abdominal pain that can radiate to the back and may be accompanied by nausea and vomiting. Acute pancreatitis is typically confirmed by the presence of elevated levels of serum amylase and/or lipase and characteristic findings by radiological imaging.
- **Discontinue Byetta if pancreatitis is suspected.** If pancreatitis is confirmed, do not restart Byetta unless an alternative etiology for the pancreatitis is identified.

Information for the patient: *Physicians who prescribe Byetta should discuss with their patients:*

Byetta is a medicine given by injection to help treat adults with type 2 diabetes. Commonly reported side effects of Byetta include nausea, vomiting, diarrhea, indigestion and upper abdominal discomfort. However, the presence of unexplained, severe abdominal pain, with or without nausea and vomiting, raises the suspicion of acute pancreatitis, a potentially serious condition that requires prompt medical attention. Therefore, patients taking Byetta should promptly seek medical care if they experience unexplained severe abdominal pain with or without nausea and vomiting.

Background Information and Data

FDA has reviewed 30 postmarketing reports of acute pancreatitis in patients treated with Byetta. Twenty-seven of the 30 patients had at least one other risk factor for acute pancreatitis such as gallstones, severe hypertriglyceridemia, and alcohol use. In six patients the symptoms of pancreatitis began or worsened soon after the dose of Byetta was increased from 5 micrograms twice daily to 10 micrograms twice daily. Twenty-one patients were hospitalized. There were no reports of hemorrhagic or necrotizing pancreatitis. However, five patients developed serious complications including dehydration and renal failure; suspected ileus; phlegmon; and ascites. Twenty-two of the 30 reports indicated that the patients improved after discontinuing Byetta.

Details in three reports indicated that the symptoms of acute pancreatitis returned when Byetta was restarted. Nausea and vomiting returned in two patients when Byetta was restarted. In a third patient, abdominal pain returned when Byetta was restarted and abated after Byetta was permanently discontinued.

FDA has asked and the maker of Byetta, Amylin Pharmaceuticals, Inc. has agreed to include information about acute pancreatitis in the Precautions section of the product label.

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