Safety

Byetta (exenatide)

Audience: Endocrinologists, other healthcare professionals, consumers

[UPDATED 08/18/2008] 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 signs or symptoms that distinguish acute hemorrhagic or necrotizing pancreatitis associated with Byetta from the less severe form of pancreatitis. 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.

[UPDATED 02/27/2008] Dear Healthcare Professional letter posted.

[January, 2008 - Label - Amylin Pharmaceuticals, Inc.]
[October 16, 2007 - Information for Healthcare Professionals - FDA]
[October, 2007 - Letter - Amylin Pharmaceuticals, Inc. and Eli Lilly and Company]