

BYETTA® (exenatide) injection Fact Sheet

Background

BYETTA (exenatide) injection is indicated for use as a stand-alone medication (monotherapy) along with diet and exercise to improve glycemic control in adults with type 2 diabetes.

At the end of 2008, the American Diabetes Association (ADA) and the European Association for the Study of Diabetes (EASD) updated treatment guidelines to include BYETTA, acknowledging the approach of treating diabetes with glucose control therapies that promote weight loss without increasing hypoglycemia. In addition, the American Association of Clinical Endocrinologists (AACE) and the American College of Endocrinology (ACE) in October 2009 issued a new type 2 diabetes algorithm in which GLP-1 agonists are recommended for use earlier in the treatment continuum based on effectiveness and overall safety profile.¹

Approval

BYETTA was approved for marketing in the United States in April 2005 as adjunctive therapy with certain oral medications and in October 2009 as monotherapy along with diet and exercise. Since market availability (June 2005), more than 1 million patients have used BYETTA.²

BYETTA has a proven history with 4 years on the market, over 10 million prescriptions written,³ and 6.5 years of clinical experience. BYETTA offers powerful, sustained A1C reductions with potential weight loss.

GLP-1 Class

BYETTA is the first compound in a class of drugs known as GLP-1 receptor agonists. It mimics several of the actions of a naturally occurring hormone in the body called glucagon-like peptide-1 (GLP-1), which stimulates insulin release from the pancreas, regulates glucagon levels, reduces food intake, and slows the rate of gastric emptying.

Dosing

BYETTA is available in a simple-to-use, twice-a-day, fixed-dose pen device. Two prefilled pens are available to deliver unit doses of 5 mcg or 10 mcg. Each prefilled pen will deliver 60 doses to provide 30 days of twice daily administration (BID).

Marketing

BYETTA was developed and is distributed by Amylin Pharmaceuticals, Inc. and Eli Lilly and Company. In 2002, the two companies entered into a strategic agreement and formed a collaboration, which is referred to as the Amylin/Lilly Alliance. The Alliance is committed to developing treatment options for patients with diabetes. In addition to BYETTA, Amylin and Lilly have partnered with Alkermes, Inc., for other development opportunities for exenatide in the treatment of type 2 diabetes.

About BYETTA®

About BYETTA (exenatide) injection

BYETTA is the first FDA-approved GLP-1 receptor agonist for the treatment of type 2 diabetes. BYETTA exhibits many of the same effects as the human incretin hormone glucagon like peptide-1 (GLP-1). GLP-1 improves blood sugar after food intake through multiple effects that work in concert on the stomach, liver, pancreas and brain.

BYETTA is an injectable prescription medicine that may improve blood sugar (glucose) control in adults with type 2 diabetes mellitus, when used with a diet and exercise program. BYETTA is not insulin and should not be taken instead of insulin. BYETTA is not recommended to be taken with insulin. BYETTA is not for people with type 1 diabetes or people with diabetic ketoacidosis.

BYETTA provides sustained A1C control and low incidence of hypoglycemia when used alone or in combination with metformin or a thiazolidinedione, with potential weight loss. BYETTA is not a weight-loss product. BYETTA was approved in April 2005 and has been used by more than 1 million patients since its introduction. For full prescribing information, visit www.BYETTA.com.

Important Safety Information for BYETTA

Important Safety Information for BYETTA

Based on postmarketing data, BYETTA has been associated with acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. The risk for getting low blood sugar is higher if BYETTA is taken with another medicine that can cause low blood sugar, such as a sulfonylurea. BYETTA should not be used in people who have severe kidney problems, and should be used with caution in people who have had a kidney transplant. Patients should talk with their healthcare provider if they have severe problems with their stomach, such as delayed emptying of the stomach (gastroparesis) or problems with digesting food. Severe allergic reactions can happen with BYETTA.

The most common side effects with BYETTA include nausea, vomiting, diarrhea, dizziness, headache, feeling jittery, and acid stomach. Nausea most commonly happens when first starting BYETTA, but may become less over time.

These are not all the side effects from use of BYETTA. A healthcare provider should be consulted about any side effect that is bothersome or does not go away.

For Prescribing Information and Medication Guide, visit www.BYETTA.com.

###

References:

1. Rodbard H, Jellinger P, Davidson J, Einhorn D, Garber A, Grunberger G, Handelsman Y, Horton E, Lebovitz H, Levy P, Moghissi E, Schwartz S. Statement by an American Association of Clinical Endocrinologists/American College of Endocrinology Consensus Panel on Type 2 Diabetes Mellitus: An Algorithm for Glycemic Control. *Endocrine Practice*. 2009; 15(6): 540-559.

2. SDI data, March 2009.

3. IMS Health data, October 2009.

02-09-9018-C ©2009 AMYLIN PHARMACEUTICALS, INC. AND LILLY USA, LLC.

PRINTED IN USA. ALL RIGHTS RESERVED.

BYETTA is a registered trademark of Amylin Pharmaceuticals, Inc.