



BYETTA® (exenatide) injection Fact Sheet

Background BYETTA® (exenatide) injection is a twice-daily injectable treatment that may improve blood sugar (glucose) control in adults with type 2 diabetes, when used with a diet and exercise program. BYETTA was the first glucagon-like peptide-1 (GLP-1) receptor agonist to be approved by the U.S. Food and Drug Administration (FDA) for the treatment of type 2 diabetes. Since market availability in June 2005, more than 1.8 million patients have used BYETTA in more than 70 countries worldwide. BYETTA provides sustained A1C control with potential weight loss (BYETTA is not a weight-loss product).

In 2008, the American Diabetes Association and the European Association for the Study of Diabetes (EASD) consensus panel updated treatment guidelines to include GLP-1 receptor agonists, 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) consensus treatment panel in 2009 issued a new type 2 diabetes algorithm in which GLP-1 receptor agonists are recommended for use earlier in the treatment continuum based on effectiveness and overall safety profile.¹

GLP-1 Class GLP-1 receptor agonists mimic several of the actions of a naturally occurring hormone in the body called GLP-1. GLP-1 stimulates insulin release from the pancreas, regulates glucagon levels, reduces food intake and slows the rate of gastric emptying.

Approvals and Clinical Trial Experience BYETTA was approved in the U.S. in April 2005 as adjunctive therapy with certain oral medications. The FDA approved expanded uses for BYETTA as a stand-alone therapy (monotherapy) along with diet and exercise in 2009 and as an add-on therapy to insulin glargine in 2011.

The initial approval of BYETTA was based on three, 30-week controlled clinical studies in the AMIGO program. The approval of BYETTA as a monotherapy treatment and as an add-on therapy to insulin glargine was based on two additional clinical studies.^{2,3}

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

Marketing In the U.S., BYETTA is marketed by Amylin Pharmaceuticals, Inc.

**About
BYETTA
(exenatide)
injection**

BYETTA was the first glucagon-like peptide-1 (GLP-1) receptor agonist to be approved by the FDA for the treatment of type 2 diabetes. BYETTA exhibits many of the same effects as the human incretin hormone 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. It can also be used with metformin, a sulfonylurea, a thiazolidinedione or Lantus® (insulin glargine), which is a long-acting insulin. BYETTA is not insulin and should not be taken instead of insulin. BYETTA should not be taken with short- and/or rapid-acting insulin. BYETTA is not for people with type 1 diabetes or people with diabetic ketoacidosis. BYETTA has not been studied in patients with a history of pancreatitis. Other antidiabetic therapies should be considered for these patients.

BYETTA provides sustained A1C control with potential weight loss (BYETTA is not a weight-loss product). BYETTA was approved in the U.S. in April 2005 and in Europe in November 2006 and has been used by more than 1.8 million patients since its introduction. See important safety information below. Additional information about BYETTA is available at www.BYETTA.com.

**Important
Safety
Information
for BYETTA
(exenatide)
injection**

Based on post-marketing data, BYETTA has been associated with acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. Patients should be observed for signs and symptoms of pancreatitis after initiation or dose escalation of BYETTA. The risk of getting low blood sugar is higher if BYETTA is taken with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. The dose of sulfonylurea or insulin may need to be lowered while BYETTA is used. 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. Antibodies may develop with use of BYETTA. Patients who develop high titers to exenatide could have worsening or failure to achieve adequate glycemic control. Consider alternative therapy if this occurs. Severe allergic reactions can happen with BYETTA. There have been no clinical studies establishing conclusive evidence of macrovascular risk reduction with BYETTA or any other antidiabetic drug.

The most common side effects with BYETTA include nausea, vomiting, diarrhea, feeling jittery, dizziness, headache, acid stomach, constipation and weakness. 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 additional important safety information about BYETTA, please see the full Prescribing Information (www.BYETTA.com/pi) and Medication Guide (www.BYETTA.com/mg).

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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 Moretto TJ, Milton DR, Ridge TD, et al. Efficacy and tolerability of exenatide monotherapy over 24 weeks in antidiabetic drug-naïve patients with type 2 diabetes: a randomized, double-blind, placebo-controlled, parallel-group study. *Clin Ther*. 2008;30:1448-60.

³ Buse JB, Bergenstal RM, Glass LC, et al. Use of twice-daily exenatide in basal insulin-treated patients with type 2 diabetes: A randomized, controlled trial. *Ann Intern Med*. 2011;154:103-112.