

Patient Information

BYETTA[®] (bye-A-tuh) **exenatide injection**

Read this Patient Information and the Pen User Manual that come with BYETTA before you start using it and each time you get a refill. There may be new information. This Patient Information does not take the place of talking with your healthcare provider about your medical condition or your treatment. **If you have questions about BYETTA after reading this information, ask your healthcare provider or pharmacist.**

What is BYETTA?

BYETTA is an injectable medicine used to improve glucose (blood sugar) control in adults with type 2 diabetes. BYETTA can be used with metformin, a sulfonylurea, or a thiazolidinedione. There are many antidiabetic medicines that contain a sulfonylurea. Ask your healthcare provider or pharmacist if you are not sure if your antidiabetic medicine contains a sulfonylurea.

BYETTA is not a substitute for insulin in patients whose diabetes requires insulin treatment. BYETTA has not been studied in children.

Who should not use BYETTA?

Do not use BYETTA if:

- You are allergic to exenatide or any of the other ingredients in BYETTA. See the end of this Patient Information for a complete list of ingredients.

What should I tell my healthcare provider before using BYETTA?

Tell your healthcare provider about all of your medical conditions including if you:

- Have severe problems with your stomach (gastroparesis) or food digestion. BYETTA slows stomach emptying so food passes more slowly through your stomach.
- Have severe kidney disease or you are on dialysis.
- Are pregnant or planning to become pregnant. It is not known if BYETTA may harm your unborn child.

- Pregnancy Registry: Amylin Pharmaceuticals, Inc. has a registry for women who have taken BYETTA during pregnancy. The purpose of this registry is to collect information about the results of the pregnancy and the health of the child. If you took BYETTA at any time during pregnancy you are encouraged to enroll by calling (800) 633-9081.
- Are breastfeeding. It is not known if BYETTA passes into your milk and can harm your child.

Tell your healthcare provider about all the medicines you take including prescription and nonprescription medicines, vitamins, and herbal supplements.

BYETTA slows stomach emptying and can affect medicines that need to pass through the stomach quickly. Ask your healthcare provider if the time at which you take any of your oral medicines (for example, birth control pills, antibiotics) should be changed.

Know the medicines you take. Keep a list of them with you to show your healthcare provider and pharmacist each time you get a new medicine.

How should I use BYETTA?

See the accompanying Pen User Manual for instructions for using the BYETTA Pen and injecting BYETTA. BYETTA comes in a prefilled pen. Two prefilled pens (5 mcg or 10 mcg) are available, depending on your prescribed dose (5 mcg or 10 mcg, twice a day). Each pen has 60 doses to provide 30 days of twice-a-day injections. You must do a “New Pen Set-Up” (see User Manual) one time only, when starting a new prefilled BYETTA Pen. If you do this “New Pen Set-Up” before each injection, you will run out of medicine before 30 days.

- Use BYETTA exactly as prescribed by your healthcare provider. Your dose may be increased after using BYETTA for 30 days. Do not change your dose unless your healthcare provider has told you to change your dose. Your healthcare provider must teach you how to inject BYETTA before you use it for the first time. If you have questions or do not understand the instructions, talk to your healthcare provider or pharmacist.
- Pen needles are not included. You may need a prescription to purchase pen needles from your pharmacist. Ask your healthcare provider which needle length and gauge is best for you.
- Inject your dose of BYETTA under the skin (subcutaneous injection) of your upper leg (thigh), stomach area (abdomen), or upper arm.
- BYETTA is injected, twice a day, at any time within the 60 minutes (1 hour) **before** your morning and evening meals (or before the two main meals of the day, approximately 6 hours or more apart). **Do not** take BYETTA after your meal.
- If you miss a dose of BYETTA, skip that dose and take your next dose at the next prescribed time. **Do not** take an extra dose or increase the amount of your next dose to make up for the one you missed.

- If you use too much BYETTA, call your healthcare provider or poison control center right away. You may need medical treatment right away. Too much BYETTA can cause nausea, vomiting, dizziness, or symptoms of low blood sugar.

What are the possible side effects of BYETTA?

When BYETTA is used with a medicine that contains a sulfonylurea, hypoglycemia (low blood sugar) can occur. The dose of your sulfonylurea medicine may need to be reduced while you use BYETTA. The signs and symptoms of low blood sugar may include headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, sweating, and feeling jittery. Your healthcare provider should tell you how to treat low blood sugar.

The most common side effects with BYETTA include nausea, vomiting, diarrhea, dizziness, headache, feeling jittery, and acid stomach. Nausea is most common when first starting BYETTA, but decreases over time in most patients. Talk to your healthcare provider if you experience the following **severe and persistent** symptoms, alone or in combination, because they could be signs of serious medical conditions: abdominal pain, nausea, vomiting, or diarrhea.

BYETTA may reduce your appetite, the amount of food you eat, and your weight. No changes in your dose are needed for these side effects.

Talk to your healthcare provider about any side effect that bothers you or that does not go away.

These are not all the side effects with BYETTA. Ask your healthcare provider or pharmacist for more information.

How should I store BYETTA?

- Store your new, unused BYETTA Pen in the original carton in a refrigerator at 36°F to 46°F (2°C to 8°C) protected from light. Do not freeze. Throw away any BYETTA Pen that has been frozen.
- After first use, your BYETTA Pen can be kept at a temperature not to exceed 77°F (25°C). Do not freeze. Do not use BYETTA if it has been frozen. BYETTA should be protected from light.
- Use a BYETTA Pen for only 30 days. Throw away a used BYETTA Pen after 30 days, even if some medicine remains in the pen.
- BYETTA should not be used after the expiration date printed on the label.
- Do not store the BYETTA Pen with the needle attached. If the needle is left on, medicine may leak from the BYETTA Pen or air bubbles may form in the cartridge.
- **Keep your BYETTA Pen, pen needles, and all medicines out of the reach of children.**

General information about BYETTA

Medicines are sometimes prescribed for conditions that are not listed in the Patient Information. Do not use BYETTA for a condition for which it was not prescribed. Do not give BYETTA to other people, even if they have the same symptoms you have. It may harm them.

Your food and exercise plan, along with your periodic blood sugar testing and scheduled A1C (also known as HbA_{1C}) checks, will continue to be important in managing your diabetes while you are taking BYETTA.

This Patient Information includes the most important information you should know about using BYETTA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about BYETTA that is written for health professionals.

- More information on BYETTA can be found at <http://www.BYETTA.com>.
- BYETTA Customer Service is available 24 hours a day at 1-800-868-1190.

What are the ingredients in BYETTA?

Active Ingredient: exenatide

Inactive Ingredients: metacresol, mannitol, glacial acetic acid, and sodium acetate trihydrate in water for injection.

Manufactured for Amylin Pharmaceuticals, Inc., San Diego, CA 92121
Marketed by Amylin Pharmaceuticals, Inc. and Eli Lilly and Company

Literature Revised June 2008

BYETTA is a registered trademark of Amylin Pharmaceuticals, Inc.

© 2005, 2008 Amylin Pharmaceuticals, Inc. All rights reserved.

823010-AA