

MEDICATION GUIDE

BYETTA® (bye-A-tuh) (exenatide) Injection

Read this Medication Guide 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 Medication Guide 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 the most important information I should know about BYETTA?

Do not share your BYETTA Pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

Serious side effects can happen in people who take BYETTA, including inflammation of the pancreas (pancreatitis) which may be severe and lead to death.

Before taking BYETTA, tell your healthcare provider if you have had:

- pancreatitis
- stones in your gallbladder (gallstones)
- a history of alcoholism
- high blood triglyceride levels

These medical conditions can make you more likely to get pancreatitis in general. It is not known if having these conditions will lead to a higher chance of getting pancreatitis while taking BYETTA.

While taking BYETTA:

Call your healthcare provider right away if you have pain in your stomach area (abdomen) that is severe, and will not go away. The pain may happen with or without vomiting. The pain may be felt going from your abdomen through to your back. These may be symptoms of pancreatitis.

What is BYETTA?

- 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.
- You should not take BYETTA instead of insulin.
- The use of BYETTA with short acting insulin is not recommended.
- The use of BYETTA with rapid acting insulin is not recommended.
- BYETTA is not for people with type 1 diabetes or people with diabetic ketoacidosis.
- It is not known if BYETTA is safe and effective in children.
- BYETTA has not been studied in people who have pancreatitis.
- BYETTA should not be used in people who have severe kidney problems.

Who should not use BYETTA?

Do not use BYETTA if:

- you have had an allergic reaction to exenatide or any of the other ingredients in BYETTA. See the end of this Medication Guide for a complete list of ingredients in BYETTA.

Symptoms of a severe allergic reaction with BYETTA may include:

- swelling of your face, lips, tongue, or throat
- problems breathing or swallowing
- severe rash or itching
- fainting or feeling dizzy
- very rapid heartbeat

What should I tell my healthcare provider before using BYETTA?

Before taking BYETTA, tell your healthcare provider if you:

- have or have had pancreatitis, stones in your gallbladder (gallstones), a history of alcoholism, or high blood triglyceride levels.
- have severe problems with your stomach, such as delayed emptying of your stomach (gastroparesis) or problems with digesting food.
- have or have had kidney problems, or have had a kidney transplant.
- have any other medical conditions.
- are pregnant or plan to become pregnant. It is not known if BYETTA will harm your unborn baby

Pregnancy Registry: A registry has been implemented for women who take BYETTA during pregnancy. The purpose of this registry is to collect

information about the health of you and your baby. If you take BYETTA at any time during pregnancy you may enroll in this registry by calling 1-800-633-9081.

- are breastfeeding or plan to breast-feed. It is not known if BYETTA passes into your breast milk. You and your healthcare provider should decide if you will take BYETTA or breast-feed. You should not do both without talking with your healthcare provider first.

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. BYETTA may affect the way some medicines work and some other medicines may affect the way BYETTA works.

Especially tell your healthcare provider if you take:

- other anti-diabetes medicines, especially sulfonylurea medicines or insulin.
- birth control pills that are taken by mouth (oral contraceptives). BYETTA may lower the amount of the medicine in your blood from your birth control pills and they may not work as well to prevent pregnancy. Take your birth control pills at least one hour before your injection of BYETTA. If you must take your birth control pills with food, take it with a meal or snack where you do not also take BYETTA.
- an antibiotic. Take antibiotic medicines at least one hour before taking BYETTA. If you must take your antibiotic with food, take it with a meal or snack where you do not also take BYETTA.
- warfarin sodium (Coumadin®, Jantoven®).
- a blood pressure medicine.
- a water pill (diuretic).
- a pain medicine.
- lovastatin (Altoprev®, Mevacor®, Advicor®).

Ask your healthcare provider if you are not sure if your medicine is listed above.

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 Pen User Manual that comes with BYETTA for instructions for using the BYETTA Pen and injecting BYETTA.

- Your healthcare provider may prescribe BYETTA alone or with certain other medicines to help control your blood sugar.

- BYETTA comes in a prefilled pen.
- Use BYETTA exactly as prescribed by your healthcare provider. 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. **Do not reuse or share your needles with other people. You may give other people a serious infection, or get a serious infection from them.**
- Inject your dose of BYETTA under the skin (subcutaneous injection) of your upper leg (thigh), stomach area (abdomen), or upper arm as instructed by your healthcare provider. **Do not inject into a vein or muscle.**
- **Do not** mix BYETTA and insulin in the same syringe or vial even if you take them at the same time.
- BYETTA is injected two times each 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 a missed dose.
- If you use too much BYETTA, call your healthcare provider or poison control center at 1-800-222-1222 right away. Too much BYETTA can cause your blood sugar to drop quickly and you may have symptoms of low blood sugar. You may need medical treatment right away. Too much BYETTA can also cause severe nausea and vomiting.
- Follow your healthcare provider's instructions for diet, exercise, and how often to test your blood sugar. If you see your blood sugar increasing during treatment with BYETTA, talk to your healthcare provider because you may need to adjust your current treatment plan for your diabetes.
- Talk to your healthcare provider about how to manage high blood sugar (hyperglycemia) and low blood sugar (hypoglycemia), and how to recognize problems that can happen with your diabetes.
- **Do not share your BYETTA Pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.**

What are the possible side effects of BYETTA?

BYETTA can cause serious side effects.

See "What is the most important information I should know about BYETTA?"

It is not known whether BYETTA, or other anti-diabetes medications, increase your risk of a heart attack or stroke.

- **Low blood sugar (hypoglycemia).** Your risk for getting low blood sugar is higher if you take BYETTA with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. The dose of your sulfonylurea or insulin medicine may need to be lowered while you use BYETTA. Signs and symptoms of low blood sugar may include:
 - headache
 - drowsiness
 - weakness
 - hunger
 - fast heart beat
 - dizziness
 - confusion
 - irritability
 - sweating
 - feeling jittery

Talk with your healthcare provider about how to treat low blood sugar.

- **Kidney problems.** BYETTA may cause new or worse problems with kidney function, including kidney failure. Dialysis or kidney transplant may be needed.
 - **While taking BYETTA:** Call your healthcare provider right away if you have nausea, vomiting, or diarrhea that will not go away, or if you cannot take liquids by mouth. You may be at increased risk for kidney problems.
- **Severe allergic reactions.** Severe allergic reactions can happen with BYETTA. Stop taking BYETTA and get medical help right away if you have any symptom of a severe allergic reaction. See **"Who should not use BYETTA?"**

The most common side effects with BYETTA include:

- nausea. Nausea most commonly happens when first starting BYETTA, but may become less over time
- vomiting
- diarrhea
- feeling jittery
- dizziness
- headache

- acid stomach
- constipation
- weakness

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.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

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).
- After first use, keep your BYETTA Pen at a temperature cooler than 77°F (25°C).
- Do not freeze your BYETTA Pen. Do not use BYETTA if it has been frozen.
- Protect BYETTA from light.
- Use a BYETTA Pen for only 30 days. Throw away a used BYETTA Pen after 30 days, even if there is some medicine left in the pen.
- Do not use BYETTA 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.
- See the BYETTA Pen User Manual for instructions about the right way to throw away your BYETTA Pen.
- **Do not reuse or share your needles with other people. You may give other people a serious infection, or get a serious infection from them.**
- **Keep your BYETTA Pen, pen needles, and all medicines out of the reach of children.**

General information about BYETTA

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. 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.

This Medication Guide 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.

For more information about BYETTA, go to www.BYETTA.com or call BYETTA Customer Service at 1-800-236-9933.

What are the ingredients in BYETTA?

Active Ingredient: exenatide

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

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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