

<p style="text-align: center;"><b>MEDICATION GUIDE</b>  <b>BYETTA® (bye-A-tuh)</b>  <b>(exenatide)</b>  <b>injection, for subcutaneous use</b></p>
<p>Read this Medication Guide and the Instructions for Use that comes 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.</p>
<p><b>What is the most important information I should know about BYETTA?</b></p> <ul style="list-style-type: none"> <li>• Serious side effects can happen in people who take BYETTA, including inflammation of your pancreas (pancreatitis). Stop using BYETTA and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back.</li> </ul>
<p><b>What is BYETTA?</b></p> <ul style="list-style-type: none"> <li>• BYETTA is an injectable prescription medicine that is used along with diet and exercise to improve blood sugar (glucose) in adults with type 2 diabetes mellitus.</li> <li>• BYETTA is not recommended for people who take exenatide or other medicines called glucagon-like peptide -1 (GLP-1) receptor agonist.</li> <li>• It is not known if BYETTA is safe and effective in children.</li> </ul>
<p><b>Who should not use BYETTA?</b>  <b>Do not use BYETTA if:</b></p> <ul style="list-style-type: none"> <li>• you have had a severe 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. See “<b>What are the possible side effects of BYETTA?</b>” for symptoms of a serious allergic reaction.</li> <li>• you have a history of low blood platelet count from using exenatide medicines (drug-induced thrombocytopenia).</li> </ul>
<p><b>Before taking BYETTA, tell your healthcare provider about all of your medical conditions, including if you:</b></p> <ul style="list-style-type: none"> <li>• have or have had problems with your pancreas.</li> <li>• have severe problems with your stomach, such as delayed emptying of your stomach (gastroparesis) or problems with digesting food.</li> <li>• are scheduled to have surgery or other procedures that use anesthesia or deep sleepiness (deep sedation).</li> <li>• are pregnant or plan to become pregnant. It is not known if BYETTA will harm your unborn baby. Tell your healthcare provider if you become pregnant while taking BYETTA. Talk to your healthcare provider about the best way to control your blood sugar if you plan to become pregnant or while you are pregnant.</li> <li>• are breastfeeding or plan to breastfeed. It is not known if BYETTA passes into your breast milk. You should talk with your healthcare provider about the best way to feed your baby while taking BYETTA.</li> </ul> <p>Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. BYETTA may affect the way some medicines work and some other medicines may affect the way BYETTA works.</p> <p><b>Before using BYETTA, talk to your healthcare provider about low blood sugar and how to manage it.</b> Tell your healthcare provider if you are taking other medicines to treat diabetes, including insulin or sulfonylureas.</p> <p>Especially tell your healthcare provider if you take:</p> <ul style="list-style-type: none"> <li>• 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 at a time when you do not also take BYETTA.</li> <li>• antibiotics. 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 at a time when you do not also take BYETTA.</li> <li>• warfarin</li> <li>• lovastatin</li> </ul> <p>Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.</p>

### How should I use BYETTA?

- Read the Instructions for Use that comes with BYETTA.
- Use BYETTA exactly as your healthcare provider tells you to.
- **Your healthcare provider should teach you how to inject BYETTA before you use it for the first time.**
- 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 muscle (intramuscularly) or vein (intravenously).
- **Inject BYETTA** two times each day, at any time within 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.
- **Do not** mix insulin and BYETTA together in the same injection.
- You may give an injection of BYETTA and insulin in the same body area (such as your stomach area), but not right next to each other.
- Change (rotate) your injection sites within the area you chose with each dose. **Do not** use the same spot for each injection.
- **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.
- If you take too much BYETTA, call your healthcare provider or Poison Help line at 1-800-222-1222 or go to the nearest hospital emergency room right away.

### What are the possible side effects of BYETTA?

**BYETTA may cause serious side effects, including:**

- See **"What is the most important information I should know about BYETTA?"**
- **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.
- **Signs and symptoms of low blood sugar may include:**
  - dizziness or light-headedness
  - sweating
  - confusion or drowsiness
  - headache
  - blurred vision
  - slurred speech
  - shakiness
  - fast heartbeat
  - anxiety, irritability, or mood changes
  - hunger
  - weakness
  - feeling jittery
- **dehydration leading to kidney problems.** Diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems. It is important for you to drink fluids to help reduce your chance of dehydration. Tell your healthcare provider right away if you have nausea, vomiting, or diarrhea that does not go away.
- **severe stomach problems.** Stomach problems, sometimes severe, have been reported in people who use BYETTA. Tell your healthcare provider if you have stomach problems that are severe or will not go away.
- **low blood platelet count (drug-induced thrombocytopenia).** BYETTA may cause the number of platelets in your blood to be reduced. When your platelet count is too low, your body cannot form blood clots. You could have serious bleeding that could lead to death. **Stop using BYETTA and call your healthcare provider right away if you have unusual bleeding or bruising.**
- **severe allergic reactions.** Stop taking BYETTA and get medical help right away if you have any symptom of a severe allergic reaction including:
  - swelling of your face, lips, tongue or throat
  - problems breathing or swallowing
  - severe rash or itching
  - fainting or feeling dizzy
  - very rapid heartbeat
- **gallbladder problems.** Gallbladder problems have happened in some people who take BYETTA. Tell your healthcare provider right away if you get symptoms of gallbladder problems, which may include:
  - pain in your upper stomach (abdomen)
  - fever
  - yellowing of skin or eyes (jaundice)
  - clay-colored stools

- **food or liquid getting into the lungs during surgery or other procedures that use anesthesia or deep sleepiness (deep sedation).** BYETTA may increase the chance of food getting into your lungs during surgery or other procedures. Tell all your healthcare providers that you are taking BYETTA before you are scheduled to have surgery or other procedures.

**The most common side effects of BYETTA include:**

- |            |                   |                |
|------------|-------------------|----------------|
| • nausea   | • feeling jittery | • indigestion  |
| • vomiting | • dizziness       | • constipation |
| • diarrhea | • headache        | • weakness     |

Talk to your healthcare provider about any side effect that bothers you or that does not go away. These are not all the possible side effects of 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.
- **Keep your BYETTA Pen, pen needles, and all medicines out of the reach of children.**

**General information about the safe and effective use of 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 that you have. It may harm them. You can ask your healthcare provider or pharmacist for information about BYETTA that is written for health professionals.

**What are the ingredients in BYETTA?**

**Active ingredient:** exenatide

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

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For more information, call 1-800-236-9933.

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

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