



















































































required surgery. Call your healthcare provider if you have any symptoms of an injection-site reaction, including severe pain, swelling, blisters, an open wound, a dark scab.

- **gallbladder problems.** Gallbladder problems have happened in some people who take BYDUREON. 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

**The most common side effects of BYDUREON BCISE may include** a bump (nodule) at the injection site and nausea.

Nausea is most common when you first start using BYDUREON BCISE but decreases over time in most people as their body gets used to the medicine.

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

These are not all the possible side effects of BYDUREON BCISE.

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

**Keep BYDUREON BCISE and all medicines out of the reach of children.**

**General information about the safe and effective use of BYDUREON BCISE.**

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use BYDUREON BCISE for a condition for which it was not prescribed. Do not give your BYDUREON BCISE to other people, even if they have the same symptoms you have. It may harm them. You can ask your pharmacist or healthcare provider for information about BYDUREON BCISE that is written for health professionals.

**What are the ingredients in BYDUREON BCISE?**

**Contents of the powder:**

**Active ingredient:** exenatide.

**Inactive ingredients:** polylactide-co-glycolide and sucrose.

**Contents of liquid (diluent):**

**Inactive Ingredients:** medium chain triglycerides.

BYDUREON, BCISE and BYETTA are trademarks of the AstraZeneca group of companies. All other marks are the marks of their respective owners.

Manufactured for:

AstraZeneca Pharmaceuticals LP  
Wilmington, DE 19850

By:

Amylin Ohio LLC  
West Chester, OH 45071 and  
Vetter Pharma-Fertigung GmbH & Co. KG  
88214 Ravensburg  
Germany

For more information about BYDUREON BCISE, go to [www.BYDUREONBCISE.com](http://www.BYDUREONBCISE.com) or call 1-800-236-9933.

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

Revised: December 2022

**INSTRUCTIONS FOR USE**  
**BYDUREON BCISE® (by-DUR-ee-on B-cise)**  
**(exenatide) extended-release injectable suspension**  
**for subcutaneous use**  
**once-weekly**



**Read the Instructions for Use before you start using BYDUREON BCISE. Before using BYDUREON BCISE, talk to your healthcare provider about how to use it the right way.**

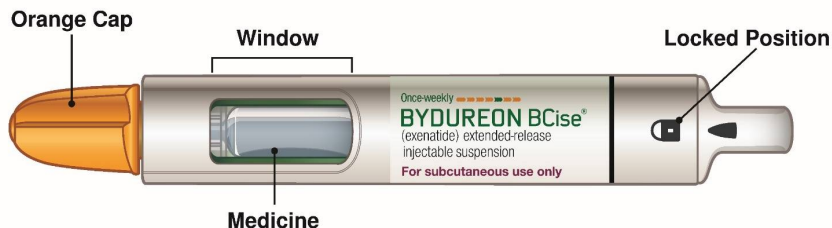
Caregivers should help children with mixing and injecting BYDUREON BCISE.

### Before You Begin

The autoinjector:

- Is a single use, fixed dose autoinjector that automatically injects your medicine.
  - Is injected 1 time per week under the skin.
  - Comes in the locked position before you use it. Do not unlock the autoinjector until you are ready to inject it.
  - Needle is hidden. You do not see it before, during, or after using the autoinjector.
- **Do not** use the autoinjector if any parts look to be broken or damaged.
  - Store flat in the refrigerator between 36°F to 46°F (2°C to 8°C).
  - BYDUREON BCISE should **not** be used by people who are blind or cannot see well, unless another person who is trained to use this device can help.
  - Keep the autoinjector, and all medicines, out of the reach of children.

### Before Use



**Figure A**

**Supplies needed to give your injection:**

- BYDUREON BCISE autoinjector
- Alcohol swab
- A clean, flat surface
- Sharps container (see “disposal” instructions at the end of these instructions)

**Step 1: Prepare for Injection**

**A. Let your autoinjector come to room temperature.**

Remove 1 autoinjector from the refrigerator and rest it flat for 15 minutes. Autoinjector can be kept at room temperature for up to 4 weeks.



**Figure B**

**B. Check the expiration date (labeled EXP) printed on the autoinjector label.**

Do not use the autoinjector past the expiration date. If the expiration date has passed, throw it away and get a new autoinjector.



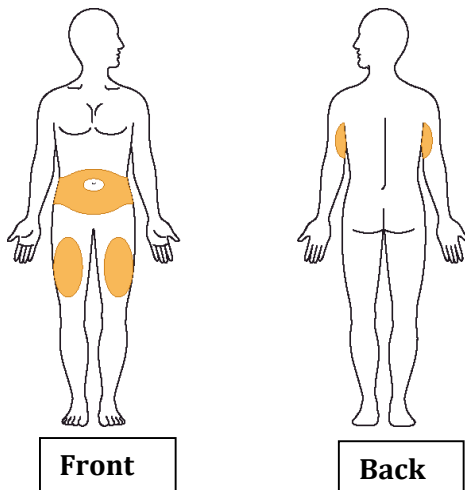
**Figure C**

**C. Wash your hands.**

**D. Choose your injection site.**

You can inject into your stomach, thigh, or back of the upper arm, see Figure D. Each week you can use the same area of your body, but choose a different injection site in that area of your body.

Clean the area with an alcohol swab.



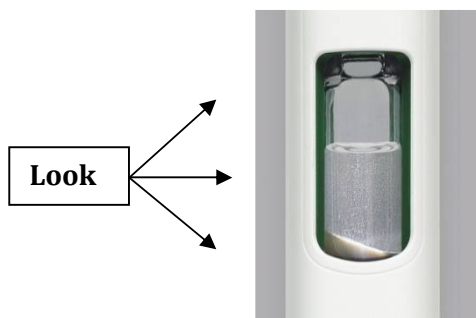


**Figure D**

**Step 2: Mix the medicine**

**A. Look in the window.**

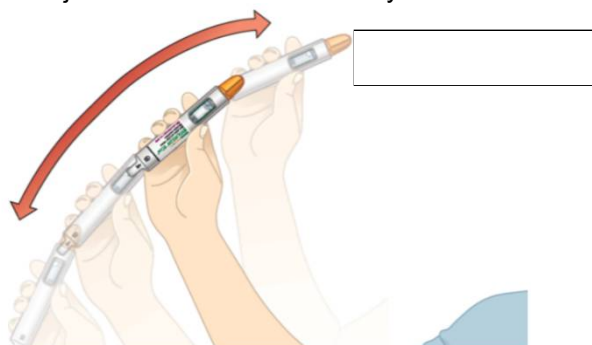
You may see white medicine along the sides, bottom or top. This means the medicine is not mixed evenly.



**Figure E**

**B. Shake the autoinjector hard,**

in an up-and-down motion, until the medicine is mixed evenly and you do not see any white medicine along the sides, bottom or top. Shake for at least 15 seconds. The autoinjector may need to be shaken longer than 15 seconds if the autoinjector has not been correctly stored flat.



**Figure F**

**C. Check the mix.**

Hold the autoinjector up to the light and look through both sides and the bottom of the window. If not mixed well, repeat Step 2 and check again.

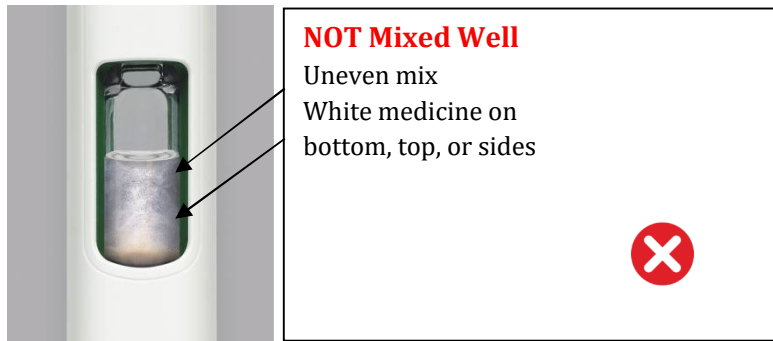


Figure G

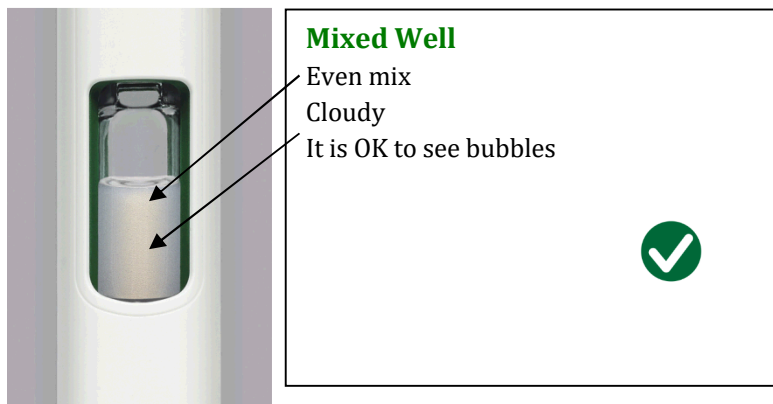


Figure H



**Do not** go to the next step unless your medicine is mixed well. To get a full dose, the medicine must be mixed well and look cloudy.

If not mixed well, continue to shake hard.

### Step 3: Prepare the Autoinjector

**Important:** After the medicine is fully mixed, you must complete the preparation steps **right away**, and inject to get the full dose. Do not save it to use later.

Only unlock the autoinjector when you are ready to inject

#### A. Unlock the autoinjector.

Hold the autoinjector up straight with the orange cap toward the ceiling. Turn the knob from the Lock to the Unlock position until you hear a click.

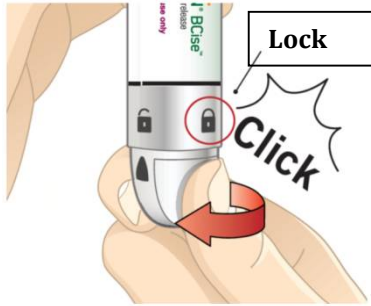


Figure I

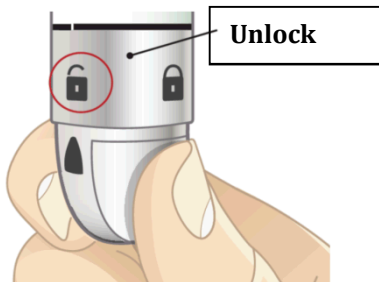


Figure J

**B. While still holding the autoinjector straight up, firmly unscrew the orange cap.**

- You may need to turn the cap a few times before it loosens (if you hear clicking you are turning in the wrong direction).
- Continue holding the autoinjector upright to prevent the medicine from accidentally leaking.
- A green shield will pop up after the cap is removed. The green shield hides the needle.

It is normal to see a few drops of liquid inside the cap. **Do not** recap the autoinjector. Throw away the cap.



Figure K

Figure L

Removed Cap

Green shield pops up

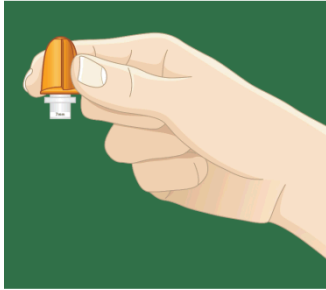


Figure M

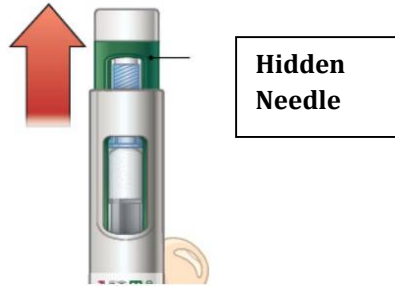


Figure N

#### Step 4: Inject the Dose

##### A. Inject and hold:

- Push the autoinjector against your skin. You will hear a “click” when the injection begins.
- Keep holding the autoinjector against the skin for 15 seconds. This is to make sure you get the full dose.

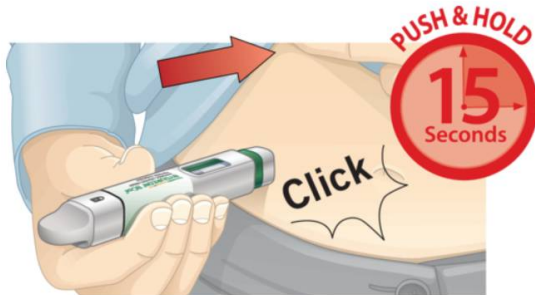


Figure O

##### B. Make sure you received your full dose.

After you receive your injection, you will see an orange rod in the window. After you lift the autoinjector from your skin, the green shield will move back up to lock over the needle. See the Common Questions and Answers for what to do if you do not see the orange rod in the window after injection.

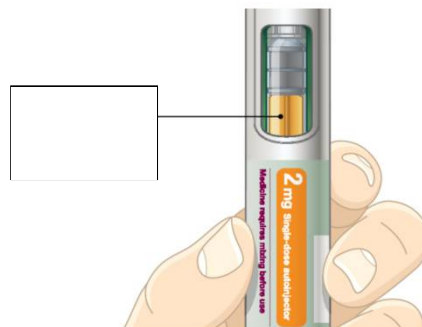


Figure P

#### Step 4: Inject the Dose (continued)

##### C. Disposal.

Put your used autoinjector in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes into your household trash. If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- Made of heavy-duty plastic
- Can be closed with a tight-fitting, puncture-resistant lid that will not let sharps come out
- Upright and stable during use
- Leak-resistant, and
- Properly labeled to warn of hazardous waste inside the container



**Figure Q**

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container. See "Common Questions and Answers" for additional disposal information.

Please keep these instructions to use for your next dose.

## **Common Questions and Answers**

### **1. Where is the needle?**

The needle is attached to the autoinjector and covered by the orange cap. When you unscrew the orange cap, the green shield keeps the needle covered until you inject. For more information, please see Figure N in Step 3B in the Instructions for Use.

### **2. How do I know if the medicine is fully mixed?**

After shaking the autoinjector, look through both sides of the window. You should not see any white medicine along the bottom, top, or sides. If you see white medicine, it is unmixed. To mix, shake the autoinjector hard until the white medicine is no longer on the bottom, top, or sides. The medicine should look even throughout.

### **3. Why do I need to hold the autoinjector upright while removing the orange cap?**

Holding the autoinjector with the orange cap straight up helps prevent the medicine from leaking. It is normal to see a few drops of medicine inside the orange cap after you unscrew it.

### **4. Why should I inject my medicine right away after mixing it?**

If you do not inject your medicine right away after mixing, the medicine may separate, and you will not get your full dose. You can re-mix your medicine if your autoinjector is in the locked position. However, after you unlock it, you must complete the preparation steps right away and inject to get the full dose. You cannot save it for later use.

#### **5. How do I know I gave myself the full dose of medicine?**

To be sure you get your full dose, press and hold the autoinjector against your skin.

You will feel the needle go into your skin. Hold the needle against your skin for 15 seconds. This will allow enough time for all the medicine to go from the autoinjector to under your skin. After removing the needle, look for the orange rod in the window as a way to tell that the dose has been given. If the orange rod does not appear contact Customer Service at 1-800-236-9933.

#### **6. Why should I store my autoinjectors flat in the refrigerator?**

Autoinjectors stored vertically (with the needle up or down) are more difficult to mix. The medicine can still be fully mixed, but it will take more shaking and more time.

#### **7. What if I do not have an FDA-cleared sharps disposal container?**

**Do not** throw away (dispose of) the autoinjector in your household trash. If you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- Made of heavy-duty plastic
- Can be closed with a tight-fitting, puncture-resistant lid, that will not let sharps come out
- Upright and stable during use
- Leak-resistant, and
- Properly labeled to warn of hazardous waste inside the container

When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and autoinjectors.

For more information about safe sharps disposal, and for specific information about sharps disposal in the state you live in, go to the FDA's website at: <http://www.fda.gov/safesharpsdisposal>.

#### **8. What if I cannot unlock the autoinjector?**

Review the Instructions for Use Step 3 to make sure you are following the right instructions, then contact Customer Service, 1-800-236-9933 for help as needed. Do not try to unlock with excessive force or tools.

#### **9. What if I cannot remove the orange cap from the autoinjector?**

Review the Instructions for Use Step 3 to make sure you are following the right instructions. You should also check that the knob is fully in the unlocked position, then contact Customer Service, 1-800-236-9933 for help as needed. Do not use tools or try to force the cap off.

#### **10. For other questions about BYDUREON BCISE:**

Visit [www.BydureonBCise.com](http://www.BydureonBCise.com).

Call Customer Service at 1-800-236-9933.

#### **How to Store BYDUREON BCISE Autoinjector**

- Store the autoinjector flat in the refrigerator between 36°F to 46°F (2°C to 8°C).
- Each autoinjector can be kept at room temperature not to exceed 86°F (30°C) for no more than a total of 4 weeks, if needed.
- Store in the packaging provided to protect from light until you are ready to prepare and use your dose.
- Do not use the autoinjector past the expiration date. The expiration date is labeled EXP.
- Keep the autoinjector clean and away from spills.

This Instructions for Use has been approved by the U.S. Food and Drug Administration. Revised: 12/2022