

INSTRUCTIONS FOR THE USER

Read these instructions carefully before use

Read also the Package Leaflet in your carton

**Bydureon 2 mg prolonged-release suspension for injection in pre-filled pen
exenatide**

Once weekly

For subcutaneous use only

Single-dose pre-filled pen

BCise is the name of the pre-filled pen device used to inject your Bydureon medicine.



Before You Begin

The Bydureon BCise pen:

- Is a single use, fixed dose pen that automatically injects your medicine.
- Comes in the locked position before you use it. Do not unlock the pen until you are ready to inject it.
- Needle is hidden. You do not see it before, during, or after using the pen.
- **Do not** use the pen if any parts look to be broken or damaged.
- Store flat in the refrigerator between 2°C to 8°C.
- Bydureon BCise pen 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 pen, and all medicines, out of the reach of children.

Before Use

Your doctor or diabetes nurse should teach you how to inject this medicine before you use it for the first time

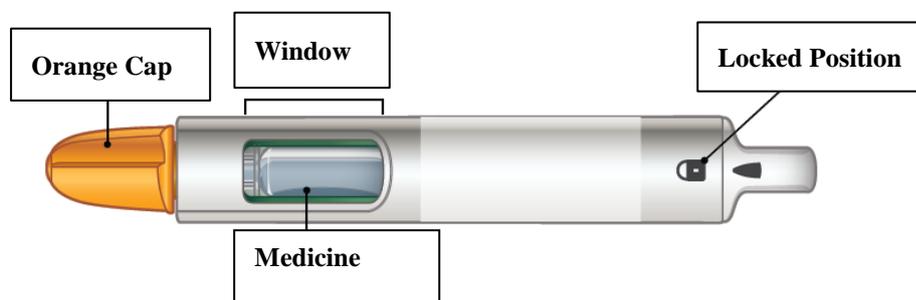


Figure A

Supplies needed to give your injection:

- Bydureon BCise pen • Alcohol swab • A clean, flat surface • Puncture-resistant container (see “disposal” instructions at the end of these instructions)

STEP 1: Prepare for injection

A. Let your pen come to room temperature.

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



Figure B

B. Check the expiration date (labelled EXP) printed on the pen label. Do not use the pen past the expiration date.

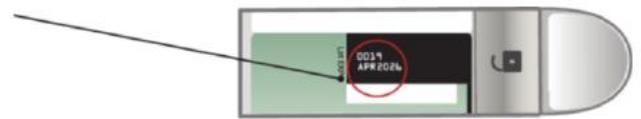


Figure C

C. Wash your hands.

D. Choose your injection site.

In either 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.

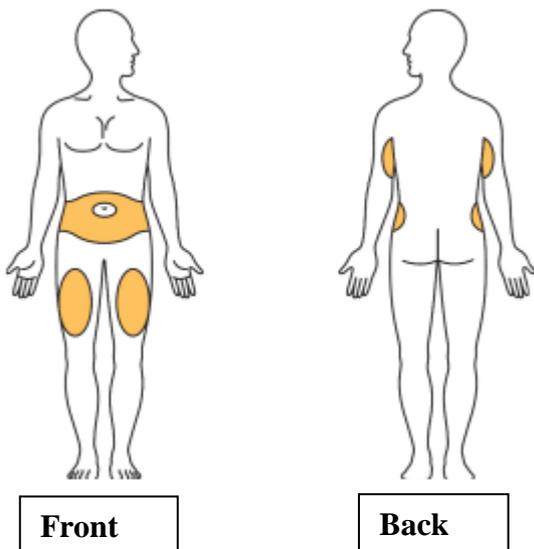


Figure D

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.

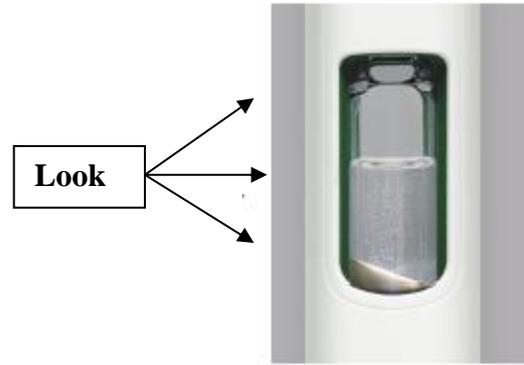


Figure E

B. Shake the pen 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.

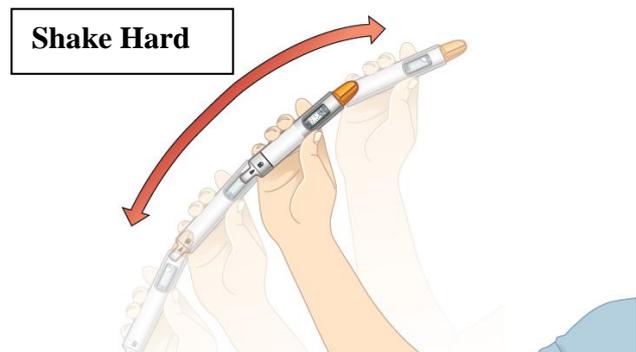


Figure F

C. Check the mix.

Hold the pen 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.

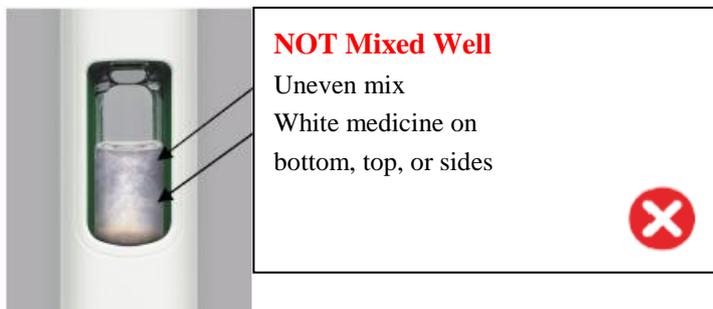


Figure G

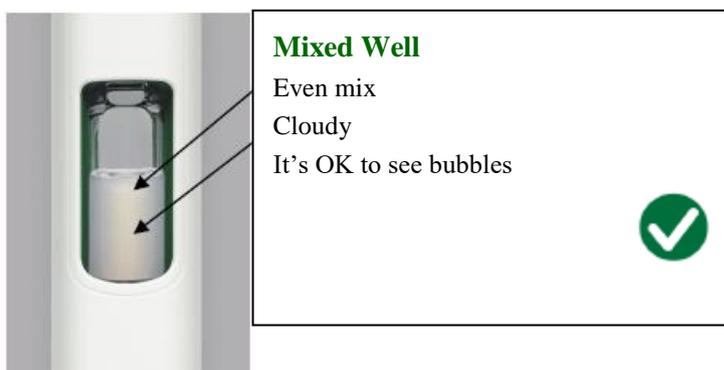


Figure H



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 Pen

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 pen when you are ready to inject.

A. Unlock the pen.

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

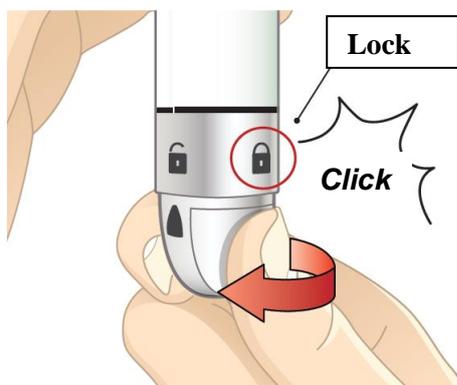


Figure I



Figure J

B. While still holding the pen 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 pen 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 pen.

Throw away the cap.

Hold **upright & firmly** unscrew



Figure K

Figure L

Removed Cap

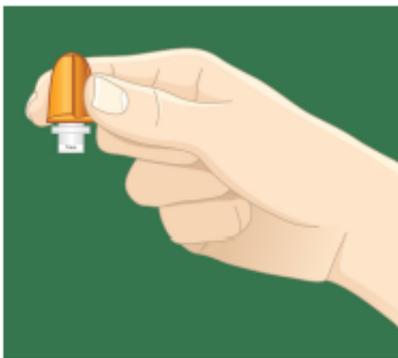


Figure M

Green shield pops up

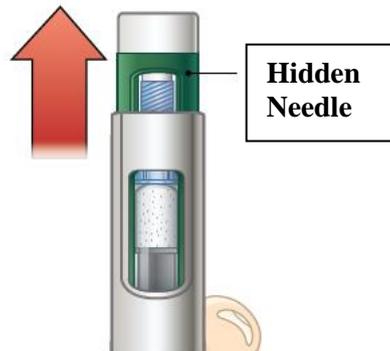


Figure N

STEP 4: Inject the Dose

A. Inject and hold:

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

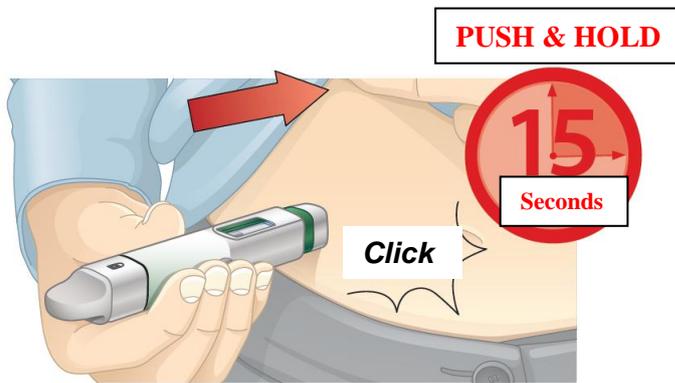


Figure O

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 pen from your skin, the green shield will move back up to lock over the needle. See the Common Questions & Answers for what to do if you do not see the orange rod after injection.



Figure P

C. Disposal.

Properly dispose of your pen right away after use, as instructed by your doctor, pharmacist or diabetes nurse.

You will need a puncture-resistant container that:

- is large enough to hold the entire pen,
- has a lid,
- does not leak,
- is properly labelled to warn of hazardous waste inside the container.

You may use a biohazard container, another hard plastic container, or a metal container.



Figure Q

Common Questions and Answers

1. Where is the needle?

The needle is attached to the pen 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 the User.

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

After shaking the pen, 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 pen hard until the white medicine is no longer on the bottom, top, or sides. The medicine should look even throughout (see pictures in Figure G and Figure H, Step 2C).

3. Why do I need to hold the pen upright while removing the orange cap?

Holding the pen 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 pen 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 pen 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 pen 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 the local representative of the Marketing Authorisation Holder (see section 6 of the Package Leaflet for a list of contacts by country).

6. Why should I store my pen flat in the refrigerator?

Pens 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. How do I dispose of my Bydureon BCise pen?

Do not throw away the pen in your household waste. You will need a puncture-resistant container that is large enough to hold the entire pen. Be sure the container has a lid. You may use a biohazard container, another hard plastic container, or a metal container. A container is not included in the carton.

Do not recycle the container with used pens. Ask your pharmacist how to safely throw it away. Do not throw the container in your household waste.

8. What if the device malfunctions and I cannot unlock it?

Review the Instructions for the User Step 3 to confirm the order of operations, then contact the local representative of the Marketing Authorisation Holder (see section 6 of the Package Leaflet for a list of contacts by country). Do not try to unlock with excessive force or tools.

9. What if the device malfunctions and I cannot remove the orange cap?

Review the Instructions for the User Step 3 to confirm the order of operations, also confirm that the knob is fully in the unlocked position, then contact the local representative of the Marketing Authorisation Holder (see section 6 of the Package Leaflet for a list of contacts by country). Do not use tools or try to force the cap off.

10. Where to learn more about Bydureon BCise pen

- **Talk with your doctor, pharmacist or diabetes nurse**
- **Read the Package Leaflet carefully.**

How to Store Bydureon BCise pen

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

Instructions for the User was last approved in 06/2019

CV 19 0121