Instructions for Use
BYDUREON® (by-DUR-ee-on) Single-Dose Tray
(exenatide extended-release) for injectable suspension

Before using Bydureon, your healthcare provider should show you how to use it the right way. Read these Instructions for Use before you start using BYDUREON Single-Dose Tray and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Getting ready
Never share your BYDUREON vials or needles with anyone else. You may give an infection to them or get an infection from them.

BYDUREON Single-Dose Tray is not for self-injection by people who are blind or cannot see well.

Supplies needed to give your BYDUREON Single-Dose Tray injection (not all supplies are included):
- 1 BYDUREON Single-Dose Tray that contains:
  ° 1 BYDUREON vial
  ° 1 Syringe
  ° 2 Needles
  ° 1 Vial connector
- alcohol swab
- a clean flat surface
- sharps container for throwing away used needles, vials, and syringes. See Step 4h “Disposing of used Needles and Syringes.”

Your guide to your BYDUREON Single-Dose Tray
- Single-dose tray

What is Inside
To take the correct dose, read each page so that you do every step in order.

This step-by-step guide is divided into 4 sections:
- Getting Started
- Connecting the Parts
- Mixing the Medicine and Filling the Syringe
- Injecting the Medicine

For Common Questions and Answers, see page 8.
How to store your Single-Dose Trays of BYDUREON

• Store your BYDUREON trays in the refrigerator at 36°F to 46°F (2°C to 8°C).
• If needed, you can keep your BYDUREON tray out of the refrigerator at 68°F to 77°F (20°C to 25°C) for up to 4 weeks.
• Protect BYDUREON from light until you are ready to prepare and use your dose.
• Do not freeze BYDUREON trays.
• Do not use BYDUREON past the expiration date. The expiration date is labeled EXP and can be found on the paper cover of each tray.
• Keep BYDUREON, and all medicines, out of the reach of children.

1. Getting Started

1a) Take a Single-Dose Tray from the refrigerator.
1b) Wash your hands. Prepare to clean your injection site with soap and water or an alcohol swab prior to injecting your medicine.

1c) Peel back the paper cover to open.
Remove the syringe. The liquid in the syringe should be clear with no particles in it. It is okay if there are bubbles.
Place the needle, vial connector package, vial, and syringe on a clean, flat surface.

1d) Pick up the needle, and twist off the blue cap.
Set the covered needle aside. You will use it later.
There is a spare needle in the tray if you need it.

1e) Pick up the vial.
Tap the vial several times against a hard surface to loosen the powder.
Use your thumb to remove the green cap.
Put the vial aside.

1f) Use your thumb to remove the green cap.
Put the vial aside.

2. Connecting the Parts

2a) Pick up the vial connector package and peel off the paper cover. Do not touch the orange connector inside.

2b) Hold the vial connector package. In your other hand, hold the vial.

2c) Press the top of the vial firmly into the orange connector.
Then lift the vial with the orange connector now attached out of the clear package.

2d) Break off the cap. Be careful not to push in the plunger.

2e) This is what the vial should now look like. Put it aside for later.

2f) Pick up the syringe. With your other hand, firmly grasp the 2 gray squares on the white cap.

2g) Just like you might break a stick, you are breaking off the cap.
3. Mixing the Medicine and Filling the Syringe

**Important:**
During these next steps, you will be mixing the medicine and filling the syringe. After you mix the medicine, you must inject it. You cannot save the mixed medicine to inject at a later time.

### 3a
With your thumb, push down the plunger until it stops. The plunger may feel like it is springing back a little.

For steps 3a to 3f, keep pushing down on the plunger with your thumb.

### 3b
Hold the plunger down and shake hard. Keep shaking until the liquid and powder are mixed well. The vial will not come off. The orange connector will keep it attached to the syringe.

Shake hard like you would shake a bottle of oil-and-vinegar salad dressing.

### 3c
When the medicine is mixed well, it should look cloudy.

If you see clumps of dry powder on the sides or bottom of the vial, the medicine is not mixed well.

Shake hard again until well mixed.

Keep pushing down on the plunger while shaking.
If you have any questions or are not sure if your BYDUREON is mixed well, call 1-877-700-7365 for help.

### 3d
Now, hold the vial upside down so the syringe is pointing up. Continue to hold the plunger in place with your thumb.

### 3e
Gently tap the vial with the other hand. Continue to hold the plunger in place.
The tapping helps the medicine drip down. It is okay if there are bubbles.
Pull the plunger down beyond the black dashed Dose Line.
This draws the medicine from the vial into the syringe. You may see air bubbles. This is normal.
A little bit of liquid may cling to the sides of the vial.

With 1 hand, hold the plunger in place so it does not move.

With the other hand, twist the orange connector to remove it from the syringe.
Be careful not to push in the plunger.

This is what the syringe should now look like.

4. Injecting the Medicine

Pick up the needle. Twist the needle onto the syringe until snug.
Do not remove the needle cover yet.

Important:
Read the next steps carefully and look closely at the pictures. This helps you get the correct dose of medicine.

Slowly push in the plunger so the top of the plunger lines up with the black dashed Dose Line.
Then, take your thumb off the plunger.

The top of the plunger must stay lined up with the black dashed Dose Line as you go through the next steps. This will help you get the correct dose of medicine.
Put aside the syringe with the needle attached.

Important:
It is normal to see a few bubbles in the mixture. The bubbles will not harm you or affect your dose.

You can inject the medicine in your stomach area (abdomen), your thigh, or the back of your upper arm.
Each week you can use the same area of your body but choose a different injection site in that area.
Gently clean the site you choose with soap and water or an alcohol swab.
Now, pick up the syringe and hold it near the black dashed Dose Line.

Pull the needle cover straight off. Do not twist. Be careful not to push in the plunger. When you remove the cover, you may see 1 or 2 drops of liquid. This is normal.

Insert the needle into your skin (subcutaneously). To inject your full dose, push down on the plunger with your thumb until it stops. Withdraw the needle. Be sure to use the injection technique recommended by your healthcare provider.

Disposing of used Needles and Syringes:
- Put your used needles and syringes in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes in your household trash.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
  - made of a heavy-duty plastic,
  - can’t be closed with a tight-fitting, puncture-resistant lid, without sharps being able to 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 pens. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA’s website at: http://www.fda.gov/safesharpsdisposal.

Please keep these Instructions for Use for your next dose.

Common Questions and Answers

If your question is about: See question number:
How soon to inject after mixing 1
Mixing the medicine 2
Air bubbles in syringe 3
Attaching the needle 4
Removing the needle cover 5
Plunger not lining up with black dashed Dose Line 6
Being unable to push the plunger down when injecting 7

1. **After I mix the medicine, how long can I wait before taking the injection?**
   You must take your injection of BYDUREON right after mixing it. If you do not inject BYDUREON right away, the medicine will start to form small clumps in the syringe. These clumps can clog the needle when you take the injection (see question 7).

2. **How do I know that the medicine is mixed well?**
   When the medicine is mixed well, it should look cloudy. There should not be any dry powder on the sides or bottom of the vial. **If you see any dry powder, shake hard while continuing to push down on the plunger with your thumb.** (This question relates to the steps shown on page 7.)
3. **I’m ready to take the injection. What should I do if I see air bubbles in the syringe?**
   It is normal for air bubbles to be in the syringe. The air bubbles will not harm you or affect your dose. BYDUREON is injected into your skin (subcutaneously). Air bubbles are not a problem with this type of injection. (This question relates to step 3f shown on page 7 and step 4c shown on page 7.)

4. **What should I do if I have trouble attaching the needle?**
   First, be sure you have removed the blue cap. Then, **twist** the needle onto the syringe until snug. To prevent losing medicine, do not push in the plunger while attaching the needle. (This question relates to step 4a on page 7.)

5. **What should I do if I have trouble removing the needle cover?**
   With one hand, hold the syringe near the black dashed Dose Line. With your other hand, hold the needle cover. **Pull the needle cover straight off.** Do not twist it. (This question relates to step 4f on page 8.)

6. **I am at step 4c. What should I do if the top of the plunger has been pushed past the black dashed Dose Line?**
   The black dashed Dose Line shows the correct dose. If the top of the plunger has been pushed past the line, you should continue from step 4d and take the injection. Before your next injection in 1 week, carefully review the instructions on pages 7 through 8.

7. **When I inject, what should I do if I cannot push the plunger all the way down?**
   This means the needle has become clogged. Remove the needle from your skin and replace it with the spare needle from your tray. Then choose a different injection site and finish taking the injection.
   
   To review how to:
   - Remove the blue cap of the needle, see page 6
   - Attach the needle, see page 7
   - Remove the needle cover and give the injection, see page 8

   If you still cannot push the plunger all the way down, remove the needle from your skin. Use a puncture-resistant container to throw away the syringe with the needle still attached. It is important that you then call 1-877-700-7365.

   To help prevent a clogged needle, always mix the medicine very well and inject right after mixing.

**Where to learn more about BYDUREON**

- **Talk with your healthcare provider**
- **Read the Medication Guide that came with your BYDUREON.** The Medication Guide can help answer your questions about BYDUREON, such as what it is used for, possible side effects, and when to take BYDUREON.
- **Enroll in BYDUREON Support for FREE ongoing help managing your diabetes.**  
  Visit www.bydureon.com or call 1-877-700-7365.

These Instructions for Use have been approved by the U.S. Food and Drug Administration.

BYDUREON® is a registered trademark of the AstraZeneca group of companies.

Manufactured for:
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By:
Amylin Ohio LLC
West Chester, OH 45071

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**Instructions for Use**

**BYDUREON® (by-DUR-ee-on) Pen**
(exenatide extended-release) for injectable suspension

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**Figure A**

Before using Bydureon Pen, your healthcare provider should show you how to use it the right way. **Read the Instructions for Use before you start using Bydureon Pen and each time you get a refill.** There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.
Getting ready

Never share your Bydureon Pen or needles with anyone else. You may give an infection to them or get an infection from them.

Bydureon Pen is not for self-injection by people who are blind or cannot see well.

Supplies needed to give your Bydureon Pen injection (not all supplies are included):

- 1 Bydureon single-use “Pen” tray that contains:
  - 1 Bydureon Pen
  - 1 custom needle
- a clean flat surface
- alcohol swab
- sharps container for throwing away used needles and Pens. See “Properly dispose of your Pen” at the end of these instructions.

How should I store Bydureon?

- Store your Bydureon Pens in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Protect pens from light until you are ready to prepare and use your dose.
- Do not use pens past the expiration date.
- Do not freeze Bydureon. Do not use Bydureon if it has been frozen.
- Keep Bydureon in its sealed tray until ready for use.
- If needed, you can keep your Bydureon Pen out of the refrigerator at 68°F to 77°F (20°C to 25°C) for up to 4 weeks.

Keep Bydureon Pen, and all medicines, out of the reach of children.

Step 1: Prepare your Bydureon Pen

Let your Pen come to room temperature.

- Remove 1 Pen from the refrigerator and let it stand at room temperature for at least 15 minutes.
- Do not use a pen past its expiration date.

Wash your hands.

Open the tray.

- Pull up on the corner tab.
- Remove the Pen and needle.
  - Do not use your Pen or needle if any parts are broken or missing.

Check the liquid in your Pen.

- Check the liquid inside the inspection window. It should be clear and free of particles. Do not use the Pen if the liquid is colored, has particles, or is not clear. Throw it away and get a new one.
  - You may see bubbles in the liquid, this is normal.

Peel off the paper tab from the needle cover.

Attach the needle to the Pen.

- Screw the needle onto the Pen by pushing and twisting clockwise until it is tight. Do not remove the needle cover yet.
Step 2: Mix your dose
Combine the medicine.

- While holding the pen straight up, slowly turn the knob. Stop when you hear the click and the green label disappears.

Firmly tap your Pen to mix.

- Hold your Pen by the end with the orange label and tap the Pen firmly against the palm of your hand.
  - DO NOT twist the white knob.
  - ROTATE your Pen every 10 taps.
  - You may need to tap your Pen 80 times or more.

Check the Bydureon mix.

- Hold your Pen up to the light and look through both sides of the mixing window. The solution should have no clumps and be uniformly cloudy (see Figure B).

### Figure B

- Not Mixed Well
  - Clumps, non-uniform solution
- Mixed Well
  - NO clumps, uniformly cloudy solution

- To get your full dose, Bydureon must be mixed well.
- If Bydureon is not mixed well, keep tapping your Pen longer and more firmly until it is mixed well.
- Do not give your Bydureon injection unless your Bydureon is mixed well.

Stop. Do Not proceed unless your medicine is mixed well.

To get your full dose the medicine must be mixed well. If it’s not mixed well, tap longer and more firmly.

Check the Bydureon mix again.

- Compare both sides of the mixing window to the photos below by holding your Pen against the page. Pay attention to the bottom surface. If you do not see clumps you are ready to inject (see Figure C).

### Figure C

- Keep Tapping
- Ready to inject

If you have any questions or are not sure if your Bydureon is mixed well, call 1-877-700-7365 for help.
Step 3: Inject your dose

Important: After the medicine is mixed well, you must inject your dose right away. You cannot save it for later use.

Choose your injection site.
- The recommended injection sites for Bydureon are your stomach (abdomen), thigh, or back of the arm.
  - Each week you can use the same area of your body but choose a different injection site in that area.
  - Gently wipe the site you choose with an alcohol swab (not included).

Twist knob to release injection button.
- Hold your Pen with the needle pointing straight up and turn the white knob until the orange label disappears and the injection button is released. Do not push the injection button yet.

Remove the needle cover.
- Pull the needle cover straight off. Do not twist the needle cover.
  - You may see a few drops of liquid on the needle or in the cover.

Inject your Bydureon.
- Insert the needle into your skin.
- Press the injection button with your thumb until you hear a “click.” Keep holding the button down and slowly count to 10 to get your full dose.

Properly dispose of your used Pen.
- Put your used needles and Pens in an FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and Pens in your household trash. See Common Questions and Answers for additional disposal information.

Common Questions and Answers:
1. How do I know that the Bydureon is mixed well?
   The Bydureon is mixed well when the liquid looks cloudy from both sides of the window. You should not see any clumps in the liquid. It may help to hold your Pen up to the light to see in the window. If you see clumps of any size keep tapping your Pen firmly against the palm of your hand until mixed.

2. I am having trouble mixing my dose. What should I do?
   Remember, before preparing your dose, leave your Pen out of the refrigerator for at least 15 minutes. This will let your Pen warm up to room temperature. It will be easier to mix Bydureon if your Pen is at room temperature.
   Be sure you are holding your Pen at the end with the knob and the orange label. This will help you grip your Pen better and tap it more firmly against your palm.
   It may also help to tap the mixing window on both sides against your palm. If you see any clumps, keep tapping.

3. After I mix Bydureon, how long can I wait before taking the injection?
   You must inject your dose of Bydureon right after mixing it. If you do not inject your Bydureon right away, small clumps of medicine may form in your Pen and you may not get your full dose.
4. I am ready to inject my dose. What should I do if I see air bubbles in the Pen?
    It is normal for air bubbles to be in your Pen. Bydureon is injected into your skin (subcutaneously). Air bubbles will not harm you or affect your dose with this type of injection.

5. What should I do if I cannot push the injection button all the way in when trying to inject my dose?
    Check that you have fully screwed on the pen needle. Also be sure you twisted the knob until it stopped, the orange label disappeared, and the injection button appears. 
    If you still cannot push the button in, this may mean that the needle is clogged. Remove the needle from your skin and replace it with the spare needle from the carton. Review how to attach the needle. Then choose a different injection site and finish taking the injection. 
    If you still cannot push the button all the way in, remove the needle from your skin. Use a puncture-resistant container to throw away the pen with the needle still attached.

6. How do I know if I injected my full dose?
    To be sure you get your full dose, press the injection button with your thumb until you hear a “click.” After the “click,” continue to hold the needle in your skin for 10 seconds. This will allow enough time for you to get your full dose.

7. What if I do not have an FDA-cleared sharps disposal container?
    Do not throw away (dispose of) loose needles and Pens 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 a heavy-duty plastic,
      ◦ can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to 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 Pens. For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal
This Instructions for Use has been approved by the U.S. Food and Drug Administration. BYDUREON® is a registered trademark of the AstraZeneca group of companies.

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