

INSTRUCTIONS FOR USE
Exenatide (ex en' a tide) Injection, USP
for subcutaneous use
250 mcg/mL, 1.2 mL

Do not share your Exenatide Injection 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.

Section 1 Read this section completely before you begin. Then, move on to Section 2—Getting Started.

WHAT YOU NEED TO KNOW ABOUT YOUR EXENATIDE INJECTION PEN



INSTRUCTIONS FOR USE

Read these instructions carefully BEFORE using your Exenatide Injection Pen. For complete dosing and safety information, also read the Exenatide Injection Medication Guide that comes with the Exenatide Injection Pen carton.

It is important that you use your pen correctly. Failure to follow these instructions completely may result in a wrong dose, a broken pen or an infection.

These instructions do not take the place of talking with your healthcare provider about your medical condition or your treatment. If you are having problems using your Exenatide Injection Pen, call toll free 1-877-835-5472.

IMPORTANT INFORMATION ABOUT YOUR EXENATIDE INJECTION PEN

- Each Exenatide Injection Pen contains enough medicine for injection two times each day for 30 days. You do not have to measure any doses, the pen measures each dose for you.
- **Do not transfer the medicine in the Exenatide Injection Pen to a syringe or vial.**
- **Do not mix Exenatide Injection and insulin in the same syringe or vial even if you take them at the same time.**
- If any part of your pen appears broken or damaged, **do not** use the pen.
- This Exenatide Injection Pen is **not** recommended for use by people who are blind or have vision problems without the help of a person trained in the proper use of the pen.
- **Follow the injection method explained to you by your healthcare provider.**
- Follow Section 2 only to set up a new pen before first use.
- Section 3 of these Instructions for Use should be used for every injection.

ABOUT PEN NEEDLES

What kinds of needles can be used with my Exenatide Injection Pen?

- **Pen needles are not included with your pen.** You may need a prescription to get them from your pharmacist.
- Use 29 (thin), 30, or 31 (thinner) gauge disposable pen needles with your Exenatide Injection Pen. Ask your healthcare provider which needle gauge and length is best for you.

Do I use a new needle for each injection?

- **Yes. 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.**
- Remove the needle from the pen immediately after you complete each injection. This will help prevent leakage of Exenatide Injection, keep out air bubbles, reduce needle clogs, and decrease the risk of infection.
- **Do not** push the injection button on your pen unless a needle is attached to the pen.

How do I throw away my needles?

Put your used needles 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 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 syringes.

Do not share your Exenatide Injection 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.

STORING YOUR EXENATIDE INJECTION PEN

How do I store my Exenatide Injection Pen?

- Prior to first use, store your unused Exenatide Injection Pen in the original carton in a refrigerator at 36° to 46°F (2° to 8°C).
- After first use, your Exenatide Injection Pen can be kept at a temperature cooler than 77°F (25°C).
- **Do not** freeze your Exenatide Injection Pen. **Do not** use Exenatide Injection if it has been frozen. Exenatide Injection should be protected from light.
- When carrying the pen away from home, store the pen at a temperature between 36° to 77°F (2° to 25°C) and keep dry.
- **Do not** store the pen with the needle attached. If the needle is left on the pen, Exenatide Injection may leak from the pen and air bubbles may form in the cartridge.

Keep your pen and needles out of the reach of children.

How long can I use an Exenatide Injection Pen?

- You can use your Exenatide Injection Pen for up to 30 days after setting up a new pen for first use. **After 30 days, throw away the Exenatide Injection Pen in a FDA-cleared sharps disposal container, even if it is not completely empty.**
- Mark the date when you first used your pen and the date 30 days later in the spaces below:

Date of First Use _____ Date to Throw Away Pen _____

- Exenatide Injection should not be used after the expiration date printed on the pen label.

How do I clean my Exenatide Injection Pen?

- Wipe the outside of the pen with a clean, damp cloth.
- White particles may appear on the outside tip of the cartridge during normal use. You may remove them with an alcohol wipe or alcohol swab.

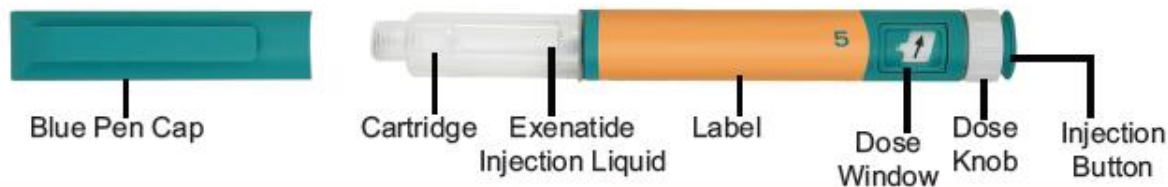
See the complete Exenatide Injection Medication Guide that comes with Exenatide Injection. For more information, call toll free 1-877-835-5472.

Section 2 Read and follow the directions in this section only after you've read Section 1—What You Need To Know About Your Exenatide Injection Pen.

GETTING STARTED

Set up your new pen just before you use it the first time. For routine use, **do not repeat this one-time-only new pen setup.** If you do, you will run out of Exenatide Injection before 30 days of use.

Exenatide Injection Pen Parts

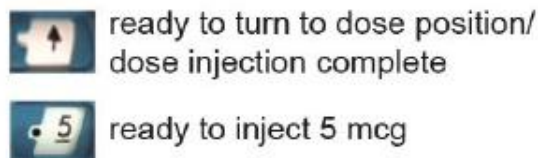


Pen Needle Parts

(Pen Needles Not Included)



Dose Window Symbols



ONE-TIME-ONLY NEW PEN SETUP

STEP 1 Check the Pen



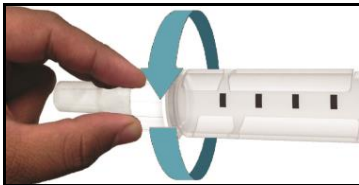
- Wash hands prior to use.
- Check pen label to make sure it is your 5 mcg pen.
- Pull off the blue pen cap.



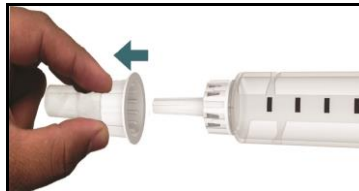
- Check Exenatide Injection in the cartridge. The liquid should be clear, colorless, and free of particles. If not, **do not use**.

Note: Small air bubbles in the cartridge are normal.

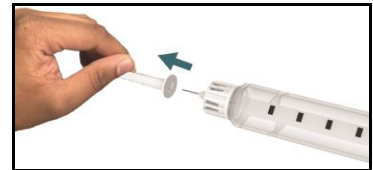
STEP 2 Attach the Needle



- Remove paper tab from outer needle shield.
- Push** outer needle shield containing the needle **straight** onto pen, then **screw** needle on until secure.





- Pull off outer needle shield. **Do not** throw away.




- Pull off inner needle shield and throw away. A small drop of liquid may appear. This is normal.


STEP 3 Dial the Dose




- Check that the  is in the dose window. If not, **turn dose knob towards you (counter-clockwise)** until the  appears in the dose window.



- Turn the dose knob away from you (clockwise)** until it stops completely and the dose knob cannot be rotated any further (clockwise). When the dose knob has been turned completely, the 5 with the line under it will be at the center of the dose window and the • will be in the nose of the dose window .

CAUTION: Make sure that the • is in the nose and the 5 with the line under it is in the center of the dose window before proceeding to the next step. 

Note: If you cannot turn the dose knob away from you to the , see **Commonly Asked Questions**, number 7, in Section 4 of these Instructions for Use.

STEP 4 Prepare the Pen




- a. Point the needle of the pen up and away from you.



PUSH & HOLD

- b. Use thumb to firmly push injection button in until it stops, then continue holding the injection button in while slowly counting to 5.
- c. If you do not see a stream or several drops come from the needle tip, repeat Steps 3 & 4.



- d. Pen preparation is complete when the  is in the center of the dose window **and** you have seen a stream or several drops come from the needle tip.

Note: If you do not see liquid after 4 times, see **Commonly Asked Questions**, number 3, in Section 4 of these Instructions for Use.

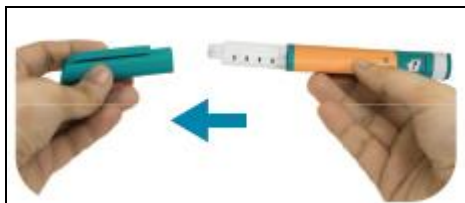
STEP 5 Complete New Pen Setup

- a. **For routine use, do not repeat this one-time-only new pen setup.** If you do, you will run out of Exenatide Injection before 30 days of use.
- b. You are now ready for your first dose of Exenatide Injection.
- c. **Go to Section 3, Step 3, for instructions on how to inject your first routine dose.**

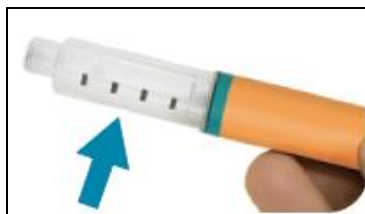
Section 3 Now that you have done the one-time-only new pen setup, follow Section 3 for all of your injections.

ROUTINE USE

STEP 1 Check the Pen



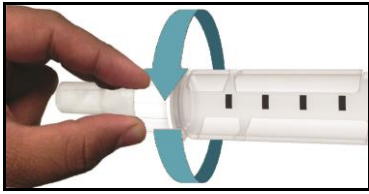
- a. Wash hands prior to use.
- b. Check pen label to make sure it is your 5 mcg pen.
- c. Pull off the blue pen cap.



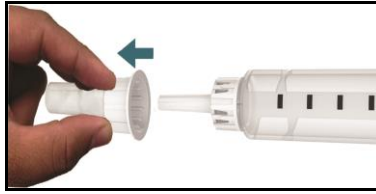
- d. Check Exenatide Injection in the cartridge.
- e. The liquid should be clear, colorless, and free of particles. If it is not, **do not use**.

Note: Small air bubbles will not harm you or affect your dose.

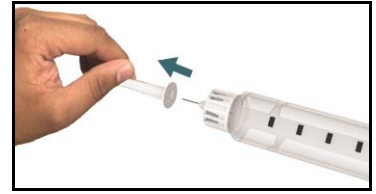
STEP 2 Attach the Needle



- Remove paper tab from outer needle shield.
- Push** outer needle shield containing the needle **straight** onto pen, then **screw** needle on until secure.

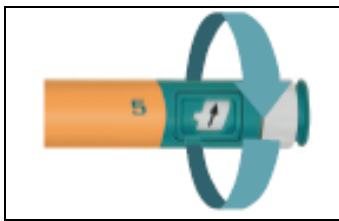




- Pull off outer needle shield. **Do not** throw away.




- Pull off inner needle shield and throw away. A small drop of liquid may appear. This is normal.


STEP 3 Dial the Dose




- Check that the  is in the dose window. If not, **turn dose knob towards you (counter-clockwise) until it stops** and the  is in the dose window.



- Turn the dose knob away from you (clockwise) until it stops completely and the dose knob cannot be rotated any further (clockwise). When the dose knob has been turned completely, the 5 with the line under it will be at the center of the dose window and the • will be in the nose of the dose window** .

CAUTION: Make sure that the • is in the nose and the 5 with the line under it is in the center of the dose window before proceeding to the next step. 

Note: If you cannot turn the dose knob away from you to the , see **Commonly Asked Questions**, number 7, in Section 4 of these Instructions for Use.

STEP 4 Inject the Dose




- Grip pen firmly.
- Insert needle into skin using the under-the-skin (subcutaneous) injection method explained by your healthcare provider.



PUSH & HOLD

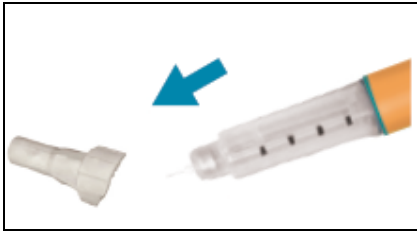
- Use thumb to firmly push injection button in until it stops.** Continue holding in the injection button while **slowly counting to 5** to get a full dose.
- Remove needle from skin.



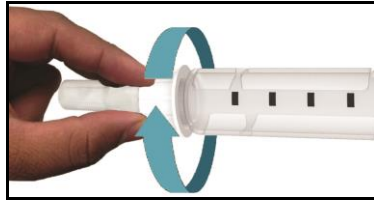
- Injection is complete when the  is in the center of the dose window.
- The pen is also now reset for the next injection dose.

Note: If you see several drops of Exenatide Injection leaking from the needle after the injection, you may not have received a complete dose. See **Commonly Asked Questions**, number 4, in Section 4 of these Instructions for Use.

STEP 5 Remove and Dispose of the Needle



- a. Carefully put the outer needle shield back over the needle.
- b. **Remove the needle after each injection.**



- c. Unscrew the needle.



- d. Throw away needles in a FDA-cleared sharps disposal container (see above “**How do I throw away my needles?**”) or as recommended by your healthcare provider.

STEP 6 Store Pen for Next Dose

- a. Replace Blue Pen Cap on pen before storage.
- b. Store your Exenatide Injection Pen at a temperature between 36° to 77°F (2° to 25°C). (See **Storing Your Exenatide Injection Pen** in Section 1 of these Instructions for Use for complete storage information.)
- c. When it is time for your next routine dose, go to **Section 3, Step 1**, and repeat Steps 1 to 6.

Section 4

COMMONLY ASKED QUESTIONS

1. **Do I need to do the One-Time-Only New Pen Setup before every dose?**
 - No. **The One-Time-Only New Pen Setup is done only once, just before each new pen is used for the first time.**
 - The purpose of the setup is to make sure that your Exenatide Injection Pen is ready to use for the next 30 days.
 - **If you repeat the One-Time-Only New Pen Setup before each routine dose, you will not have enough Exenatide Injection for 30 days.** The small amount of Exenatide Injection used in the new pen setup will not affect the 30-day supply of Exenatide Injection.
2. **Why are there air bubbles in the cartridge?**
 - A small air bubble is normal. It will not harm you or affect your dose.
 - If the pen is stored with a needle attached, air bubbles may form in the cartridge. **Do not** store the pen with the needle attached.
3. **What should I do if Exenatide Injection does not come out of the needle tip after four tries during One-Time-Only New Pen Setup?**
 - Carefully put the outer needle shield back over the needle. Remove the needle by unscrewing it. Throw away the needle properly.
 - Attach a new needle and repeat **One-Time-Only New Pen Setup, Steps 2 to 5**, in Section 2 of these Instructions for Use. Once you see several drops or a stream of liquid coming out of the tip of the needle, the setup is complete.


4. Why do I see Exenatide Injection leaking from my needle after I have finished my injection?

It is normal for a single drop to remain on the tip of your needle after your injection is complete. If you see more than one drop:

- You may not have received your full dose. **Do not inject another dose.** Talk with your healthcare provider about what to do about a partial dose.
- To make sure that you get your full dose, when you take your injections, **firmly push and hold** the injection button in and **slowly count to 5** (see **Section 3, Step 4: Inject the Dose**).

5. How can I tell when the injection is complete?

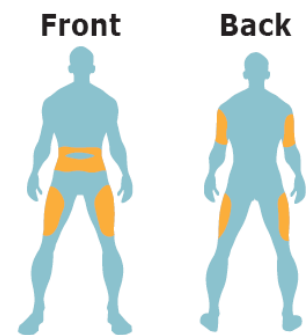
The injection is complete when:

- You have firmly pushed the injection button in all the way **until it stops**
and
- **You have slowly counted to 5** while you are still holding the injection button in and the needle is still in your skin
and
- The  is in the center of the dose window.

If you hear a click sound from your Exenatide Injection Pen, ignore it. You must follow **all** the steps listed above to make sure your injection is complete.

6. Where should I inject Exenatide Injection?

Inject Exenatide Injection into your abdomen, thigh, or upper arm using the injection method explained to you by your healthcare provider.




7. What if I cannot turn the dose knob or the injection button cannot be pushed in?


Check the symbol in the dose window. Follow the steps next to the matching symbol.

If  is in the dose window and the dose knob will not turn:

- The cartridge in your Exenatide Injection Pen may not have enough medicine to deliver a full dose. A small amount of Exenatide Injection will always stay in the cartridge. If the cartridge contains a small amount and the dose knob will not turn, your pen does not have enough Exenatide Injection and will not deliver any more doses. Get a new Exenatide Injection Pen. (or)

The injection button was not pushed in all the way during the previous dose and a complete dose was not delivered. Talk with your healthcare provider about what to do about a partial dose.

- Follow these steps to reset your pen for your next injection:
 - Firmly push the injection button in all the way **until it stops**. Keep holding the injection button in until  appears in the dose window and **slowly count to 5**. Then release the injection button.
 - If you cannot turn the dose knob, the needle may be clogged. Replace the needle and repeat the step above.
- For your next dose, be sure to **firmly push and hold** the injection button in and **slowly count to 5** before removing needle from skin.

If  is in the dose window and the injection button cannot be pushed in:

- The needle may be clogged, bent, or incorrectly attached.
- Attach a new needle. Make sure needle is on straight and screwed on all the way.
- Firmly push the injection button in all the way. Exenatide Injection should come from needle tip.

See the complete Exenatide Injection Medication Guide that comes with Exenatide Injection. For more information, call toll free 1-877-835-5472.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

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