

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

WHAT YOU NEED TO KNOW ABOUT YOUR BYETTA PEN

Byetta®

exenatide injection
250 mcg/mL, 1.2 mL



5
mcg

PEN USER MANUAL

Amylin Lilly
(logo)

PEN USER MANUAL

Read these instructions carefully **BEFORE** using your **BYETTA Pen**. For complete dosing and safety information, also read the *BYETTA Patient Information* sheet that comes with the **BYETTA 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 BYETTA Pen, call toll free 800-868-1190.

IMPORTANT INFORMATION ABOUT YOUR BYETTA PEN

- Each **BYETTA 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 BYETTA Pen to a syringe or vial.**
- If any part of your pen appears broken or damaged, do not use the pen.
- This **BYETTA 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.
- Place used needles in a closeable, puncture-resistant container. You may use a sharps container (such as a red biohazard container), a hard plastic container (such as a detergent bottle), or a metal container (such as an empty coffee can). Ask your healthcare provider for instructions on the right way to throw away (dispose of) your used pens and the container. There may be state and local laws about how you should throw away used pens and needles. Do not throw the disposal container in the household trash. Do not recycle.
- **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 this manual should be used for every injection.

ABOUT PEN NEEDLES

What kinds of needles can be used with my **BYETTA 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 BYETTA 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 needles.
- Remove the needle from the pen immediately after you complete each injection. This will help prevent leakage of BYETTA, 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?

- Throw away used needles in a puncture-resistant container or as explained to you by your healthcare provider. To learn about proper needle disposal, visit www.safeneedledisposal.org
- Do not throw away the pen with a needle attached.

Do not share your BYETTA or needles with anyone.

STORING YOUR BYETTA PEN

How do I store my BYETTA Pen?

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

- You can use your BYETTA Pen for up to 30 days after setting up a new pen for first use. **After 30 days, throw away the BYETTA Pen, 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** _____

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

How do I clean my BYETTA Pen?

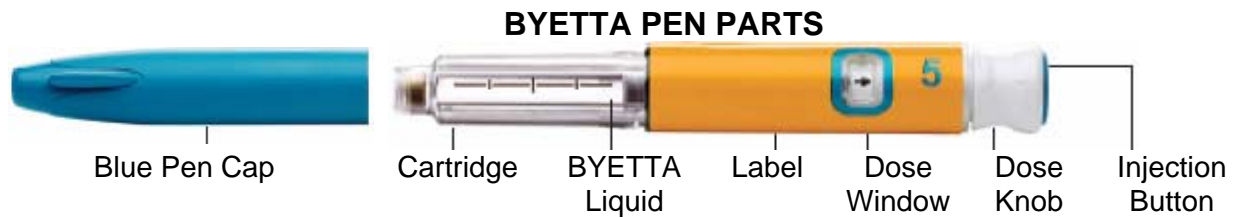
- Wipe the outside of the pen with a clean, damp cloth.
- White particles may appear on the outside tip of the cartridge during normal use. You may remove them with an alcohol wipe or alcohol swab.

See the complete
BYETTA Patient Information that comes with BYETTA. For more information,
 call toll free 800-868-1190 or visit www.BYETTA.com

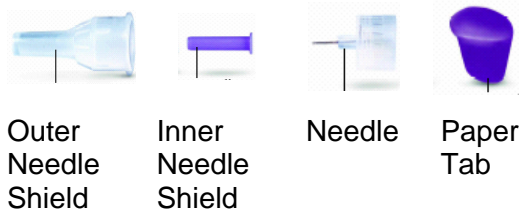
Section 2 Read and follow the directions in this section only after you've read
 Section 1—What You Need To Know About Your BYETTA Pen.

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 BYETTA before 30 days of use.



PEN NEEDLE PARTS
 (Pen Needles Not Included)



DOSE WINDOW SYMBOLS

- ready to pull dose knob out
- ready to turn to dose position
- ready to inject 5 mcg
- dose knob pushed in and ready to reset

ONE-TIME-ONLY NEW PEN SETUP

STEP A **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 BYETTA in the cartridge. The liquid should be clear, colorless, and free of particles. If not, do not use.

Note: A small air bubble in the cartridge is normal.





STEP B **Attach the Needle**




- Remove paper tab from outer needle shield.
- **Push** outer needle shield containing the needle **straight** onto the 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 C Dial the Dose




- Check that the  is in dose window. If not, turn dose knob away from you (clockwise) **until it stops** and the  is in the dose window.
- **Pull dose knob out until it stops** and the  is in the dose window.
- **Turn dose knob away from you until it stops** at . Make sure that the 5 with the line under it is in the center of the dose window.

Note: If you cannot turn the dose knob away from you to the , see **Commonly Asked Questions**, number 7, in Section 4 of this user manual.

STEP D Prepare the Pen




- Point the needle of the pen up and away from you.
- **PUSH & HOLD**
 - **Use thumb to firmly push injection button in until it stops**, then continue holding the injection button in while **slowly counting to 5**.
 - **If you do not see a stream or several drops come from the needle tip, repeat Steps C & D.**
- Pen preparation is complete when the  is in the center of the dose window AND you have seen a stream or several drops from the needle tip.

Note: If you do not see liquid after 4 times, see **Commonly Asked Questions**, number 3, in Section 4 of this user manual.

STEP E Complete New Pen Setup



- Turn dose knob away from you until it stops and the  is in the dose window.
- For routine use, do not repeat this one-time-only new pen setup. If you do, you will run out of BYETTA before 30 days of use.
- You are now ready for your first dose of BYETTA.
- Go to Section 3, Step 3, for instructions on how to inject your first routine dose.

Note: If you cannot turn the dose knob, see **Commonly Asked Questions**, number 7, Section 4 of user manual.

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



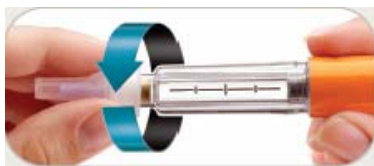
- Wash hands prior to use.
- Check pen label to make sure it is your 5 mcg pen.
- Pull off the blue pen cap.



- Check BYETTA in the cartridge.
- The liquid should be clear, colorless, and free of particles. If it is not, do not use.

Note: A small air bubble 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 the 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,





- Pull dose knob out until it stops and the




- Turn dose knob away from you until it stops

turn dose knob away from you (clockwise) **until it stops** and the  is in the dose window.

 is in the dose window.

at . Make sure that the 5 with the line under it is in the center of the dose window.

Note: If you cannot turn the dose knob away from you to the , see **Commonly Asked Questions**, number 7, in Section 4 of this user manual.

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 now ready to reset.

Note: If you see several drops of BYETTA 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 this user manual.

STEP 5 Reset the Pen



- **Turn dose knob away from you until it stops** and the  is in the dose window.

Note: If you cannot turn the dose knob, or if your pen leaks, your full dose has not been delivered. See **Commonly asked Questions**, numbers 4 and 7, in Section 4 of this user manual.

STEP 6 Remove and Dispose of the Needle



- Carefully put the outer needle shield back over the needle.
- **Remove the needle**



- Unscrew the needle.



- Throw away needles in a puncture-resistant container or as recommended by your

after each injection.

healthcare provider.

STEP 7 Store Pen for Next Dose

- Replace Blue Pen Cap on pen before storage.
- Store your BYETTA Pen at a temperature between 36°F to 77°F (2°C to 25°C). (See **Storing Your BYETTA Pen** in Section 1 of this User Manual for complete storage information.)
- When it is time for your next routine dose, go to **Section 3, Step 1**, and repeat Steps 1 - 7.

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 BYETTA 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 BYETTA for 30 days.** The small amount of BYETTA used in the new pen setup will not affect the 30-day supply of BYETTA.

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 BYETTA 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 B – E**, in Section 2 of this user manual. 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 BYETTA 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:

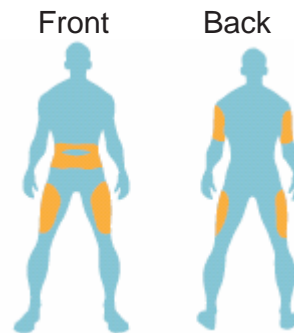
- You have firmly pushed the injection button in all the way **until it stops**
and

- **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 BYETTA Pen, ignore it. You must follow all the steps listed above to make sure your injection is complete.

6. Where should I inject BYETTA?


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



7. What if I cannot pull, turn, or push the dose knob?

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


If  is in the dose window:

- Pull the dose knob out until  appears.

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

- The cartridge in your BYETTA Pen may not have enough medicine to deliver a full dose. A small amount of BYETTA 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 BYETTA and will not deliver any more doses. Obtain a new BYETTA Pen.


If  and part of  are in the dose window and the dose knob cannot be pushed in:

- The dose knob was not turned all the way. Continue turning the dose knob away from you until  is in the center of the dose window.

If part of  and part of  are in the dose window and the dose knob 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. BYETTA should come from needle tip.

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

- The injection button was not pushed in all the way 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 and **slowly count to 5**. Then release the injection button and turn the dose knob away from you until  appears in the dose window.
 - 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.

**See the complete
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call toll free 800-868-1190 or visit www.BYETTA.com**

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Byetta®
exenatide injection

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