

Byetta[®]
exenatide injection

250 mcg/mL, 1.2 mL

5
mcg



PV 5010 UCP



Pen User Manual

BYETTA[®] exenatide injection

Prefilled Pen

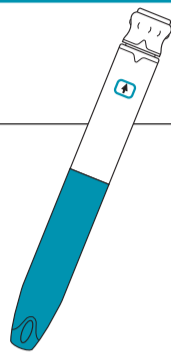
Instructions for Use

Read and follow these instructions carefully.

Also, read the *Patient Information* insert inside your pen carton.

Pen Features

- A prefilled pen containing 60 subcutaneous doses of BYETTA for 30 days of use.
- The pen delivers a fixed 5 mcg dose.



Important Notes

Read these instructions carefully before using your BYETTA Pen. Failure to follow these instructions completely may result, for example, in a wrong dose, a broken pen, or an infection.

- Check the label on your pen before each use to make sure you are using your own 5 mcg BYETTA Pen.
- **You must follow instructions in the New Pen Setup section for each new pen before its first use. The New Pen Setup is only done before each new pen is used for the first time. See Questions and Answers, number 1.**
- If any part of your pen appears broken or damaged, do not use the pen.
- This pen is not recommended for use by blind or visually impaired persons without the assistance of a person trained in the proper use of the product.
- **DO NOT TRANSFER THIS MEDICATION TO A SYRINGE.**
- Make sure the liquid in the BYETTA cartridge is clear, colorless, and free of particles. If not, do not use the pen.
- **Follow the instructions for sanitary injection technique recommended by your healthcare professional.**

Needles

- Pen needles not included. Use 29 (thin), 30, or 31 (thinner) gauge disposable pen needles with your BYETTA Pen. Ask your healthcare professional which needle gauge and length is best for you.
- Use a new needle for each injection. Remove the needle after completing each injection. This will help prevent leakage of BYETTA, keep out air bubbles, reduce needle clogs, and minimize risk of infection.
- Do not share your pen or needles.
- Be sure the needle is completely attached to the pen before use. Do not push the injection button unless a needle is attached to the pen.
- Throw away used needles in a puncture-resistant container or as directed by your healthcare professional. Do not throw away the pen with a needle attached.
- Healthcare professionals or other caregivers should follow local or institutional policies regarding needle handling.

Storage

- Store your unused BYETTA Pen in the original carton in a refrigerator at 36°F to 46°F (2°C to 8°C) protected from light. Do not freeze. Throw away any BYETTA Pen that has been frozen.
- After first use, your BYETTA Pen should be refrigerated or kept cold 36°F to 46°F (2°C to 8°C) when not in use.
- 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 space provided in this Pen User Manual.
- When carrying the pen away from home, store the pen in a way that keeps it cold 36°F to 46°F (2°C to 8°C) and dry.
- BYETTA should not be used after the expiration date printed on the label.
- Do not store the pen with the needle attached. If the needle is left on, 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.

Cleaning

- If needed, 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.



Questions and Answers

1. Do I need to do the New Pen Setup before every dose?

No. **The New Pen Setup is only done before each new pen is used for the first time.** The purpose of the setup is to check the flow of BYETTA from the tip of the needle. The small amount used in the New Pen Setup will not affect the 30-day supply of BYETTA. **If you repeat the New Pen Setup before each routine use, you will not receive 30 days of BYETTA from your pen.**

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 during New Pen Setup?

Carefully replace the outer needle shield and remove the needle. Attach a new needle, and repeat the instructions in New Pen Setup. If liquid is seen (stream or several drops), setup is complete.

4. Why is it hard to push the injection button in all the way?

The injection button may be hard to push because no needle is attached, the needle is not correctly attached, or because the needle is clogged.

Step 1) Attach a new needle. Make sure the needle is on straight and screwed on all the way.

Step 2) Hold pen with needle pointing up and push the injection button in all the way. Several drops or a tiny stream of BYETTA should come from the needle tip.

5. Why do I see BYETTA leaking from my needle after I inject?


A single drop may remain after injection is complete. This is normal.

If you see more than one drop:

- You may not have received your full dose. Do not inject another dose. Consult with your healthcare professional about how to handle a partial dose.
- To prevent this, for your next dose, make sure to **firmly push and hold** the injection button in and **slowly count to 5** (also see Step 8 of the Inject the Dose section on the other side of this Pen User Manual).

6. 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 maintaining pressure on the injection button with the needle still in your skin **and**
- the  is in the center of the dose window.


7. Why can't I pull, turn, or push the dose knob?


Check the symbol in the dose window and 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 won't turn, the cartridge in your BYETTA Pen may not have enough liquid to deliver a full dose. A small amount of BYETTA will always remain in the cartridge. If the cartridge contains a small amount or appears empty, obtain a new BYETTA Pen.

If  and part of the 5 are in the dose window and the dose knob can't be pushed in, the dose knob was not turned all the way. Continue turning until 5 clearly appears in the dose window.

If  is in the dose window and the dose knob won't turn, the injection button was not pushed in all the way and a complete dose was not delivered. Call your healthcare professional if you think you did not receive a complete dose. Follow these steps for your next injection:

Step 1) Hold the pen with needle up and firmly push the injection button in all the way until it stops. Continue applying pressure to injection button and slowly count to 5. Then turn the dose knob away from you (clockwise) until  appears in the dose window.

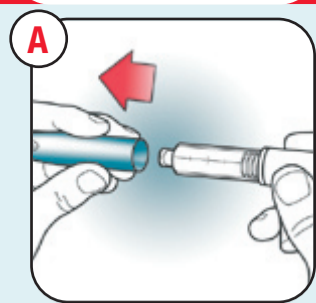
Step 2) If you cannot turn the dose knob, the needle may be clogged. Replace the needle and repeat Step 1 above.

Step 3) 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.

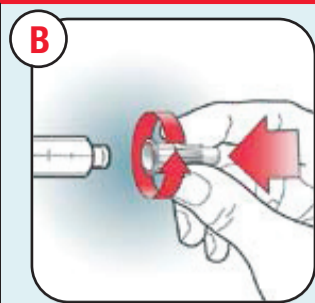
This Pen User Manual does not take the place of talking with your healthcare professional about your medical condition or your treatment. If you are having problems using your BYETTA Pen, call toll free 800-868-1190.

New Pen Setup

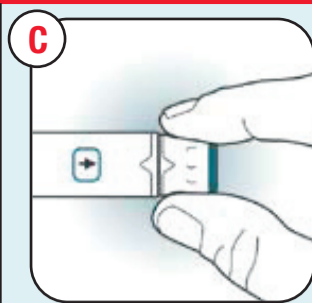
Read This before each new pen is used for the first time. Set up pen **only** at the start of its 30 days of use.



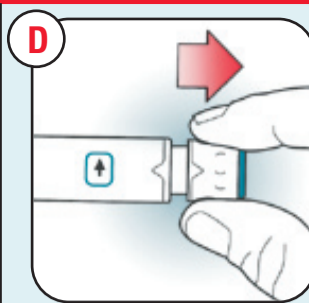
Wash hands prior to use.
Check pen label before each use to make sure it is your 5 mcg BYETTA Pen.
Pull off blue pen cap.
Check BYETTA in the cartridge. The liquid should be clear, colorless, and free of particles. If not, do not use.
A small air bubble in the cartridge is normal.



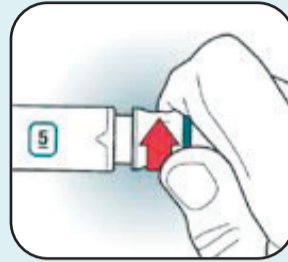
Remove paper tab from outer needle shield.
Push capped needle **straight** onto pen.
Screw needle on until secure.
Pull off outer needle shield. **Do not** throw away.
Pull off inner needle shield and throw away.



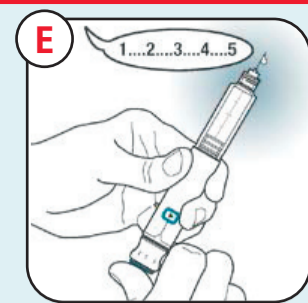
Check that is in dose window.
If not, turn dose knob away from you (clockwise) **until it stops** and is in dose window.



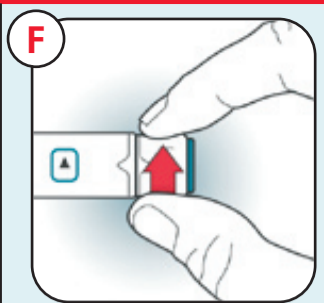
Pull dose knob out **until it stops** and is in dose window.



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



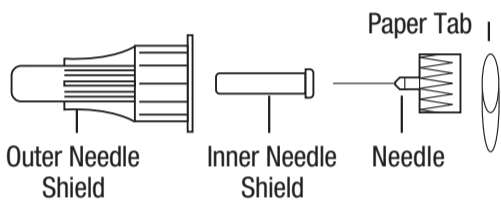
With needle pointing up,
• **firmly push** injection button in all the way **until it stops** and
• **keep holding injection button firmly** and
• **slowly count to 5.**
Watch for a stream or several drops. If none, repeat Steps C, D, and E up to three more times until a stream or several drops are seen. If BYETTA still does not come from needle tip, see **Questions and Answers**, number 3.



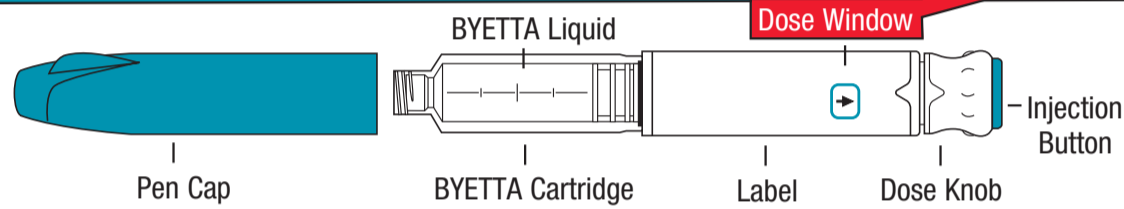
When is in the center of dose window, pen is ready to reset. Turn dose knob away from you **until it stops** and is in dose window.
Go to **Dial the Dose** section below.

Important: Do not repeat **New Pen Setup** before each routine use or you will not receive 30 days of BYETTA from your pen.

Pen Needle Parts (Needles Not Included)



BYETTA Pen Parts



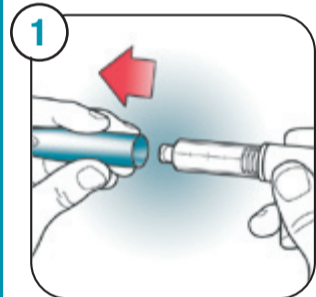
Dose Window Symbols

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

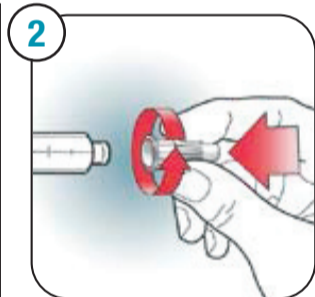
Routine Use Follow these instructions for each routine injection.

Attach the Needle

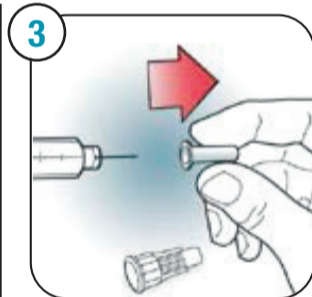
Check pen label before each use to make sure it is your 5 mcg BYETTA Pen.
Use a new needle for each injection.



Wash hands prior to use.
Pull off blue pen cap and check BYETTA in the cartridge. The liquid should be clear, colorless, and free of particles. If not, do not use.
A small air bubble will not harm you or affect your dose.

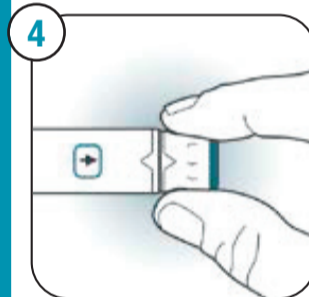


Remove paper tab from outer needle shield.
Push capped needle **straight** onto pen.
Screw needle on until secure.

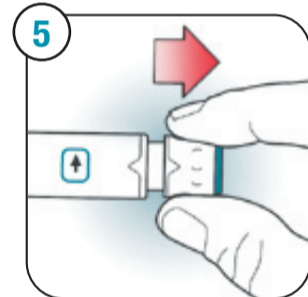


Pull off outer needle shield. **Do not** throw away.
Pull off inner needle shield and throw away.
A small drop of liquid may appear. This is normal.

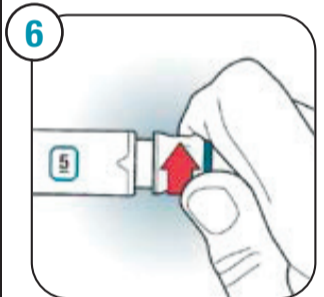
Dial the Dose



Check that is in dose window.
If not, turn dose knob away from you (clockwise) **until it stops** and is in dose window.



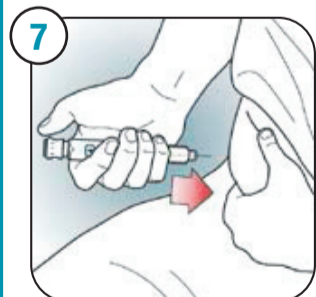
Pull dose knob out **until it stops** and is in dose window.



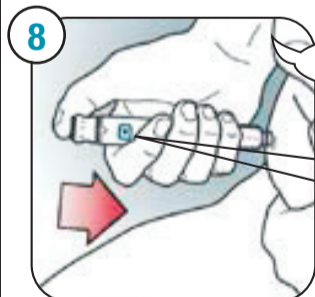
Turn dose knob away from you **until it stops** and is in dose window.

Note: If you cannot turn dose knob away from you to , see **Questions and Answers**, number 7.

Inject the Dose

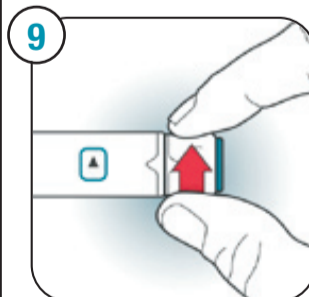


Grip the pen firmly in your hand.
Insert needle into skin using injection technique recommended by your healthcare professional.

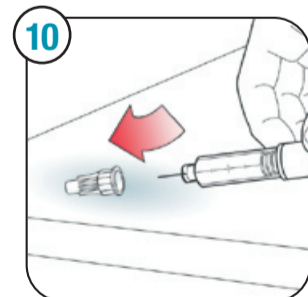


• Use thumb to **firmly push** injection button in all the way **until it stops** and
• **keep holding injection button firmly** and
• **slowly count to 5 to deliver full dose.**
Remove needle from skin.

Injection is complete when is in the center of dose window.
If several drops of BYETTA are leaking from the needle, the injection button was not pushed in all the way. See **Questions and Answers**, number 5.



Reset the pen by turning dose knob away from you (clockwise) **until it stops** and is in dose window.
Note: If you cannot turn dose knob or your pen leaks, your full dose has not been delivered. See **Questions and Answers**, numbers 5 and 7.



Carefully replace outer needle shield.
Unscrew needle and place in a puncture-resistant container.
Note: Remove needle after each injection.
Replace blue cap on pen and **store in refrigerator.**

1st use date

____ / ____ / ____
Throw away 30 days after first use date,
OR

on expiration date printed on pen label, whichever date comes first.

Throw away date

____ / ____ / ____
For additional information, call toll free 800-868-1190 or visit www.BYETTA.com

Manufactured for Amylin Pharmaceuticals, Inc., San Diego, CA 92121
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Literature revised XXXX

PV 5010 UCP



Byetta[®]
exenatide injection

250 mcg/mL, 2.4 mL

10
mcg



PV 5020 UCP



Pen User Manual

BYETTA[®] exenatide injection

Prefilled Pen

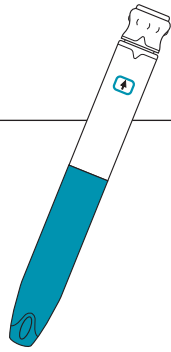
Instructions for Use

Read and follow these instructions carefully.

Also, read the **Patient Information** insert inside your pen carton.

Pen Features

- A prefilled pen containing 60 subcutaneous doses of BYETTA for 30 days of use.
- The pen delivers a fixed 10 mcg dose.



Important Notes

Read these instructions carefully before using your BYETTA Pen. Failure to follow these instructions completely may result, for example, in a wrong dose, a broken pen, or an infection.

- Check the label on your pen before each use to make sure you are using **your own** 10 mcg BYETTA Pen.
- **You must follow instructions in the New Pen Setup section for each new pen before its first use. The New Pen Setup is only done before each new pen is used for the first time. See Questions and Answers, number 1.**
- If any part of your pen appears broken or damaged, do not use the pen.
- This pen is not recommended for use by blind or visually impaired persons without the assistance of a person trained in the proper use of the product.
- **DO NOT TRANSFER THIS MEDICATION TO A SYRINGE.**
- Make sure the liquid in the BYETTA cartridge is clear, colorless, and free of particles. If not, do not use the pen.
- **Follow the instructions for sanitary injection technique recommended by your healthcare professional.**

Needles

- Pen needles not included. Use 29 (thin), 30, or 31 (thinner) gauge disposable pen needles with your BYETTA Pen. Ask your healthcare professional which needle gauge and length is best for you.
- Use a new needle for each injection. Remove the needle after completing each injection. This will help prevent leakage of BYETTA, keep out air bubbles, reduce needle clogs, and minimize risk of infection.
- Do not share your pen or needles.
- Be sure the needle is completely attached to the pen before use. Do not push the injection button unless a needle is attached to the pen.
- Throw away used needles in a puncture-resistant container or as directed by your healthcare professional. Do not throw away the pen with a needle attached.
- Healthcare professionals or other caregivers should follow local or institutional policies regarding needle handling.

Storage

- Store your unused BYETTA Pen in the original carton in a refrigerator at 36°F to 46°F (2°C to 8°C) protected from light. Do not freeze. Throw away any BYETTA Pen that has been frozen.
- After first use, your BYETTA Pen should be refrigerated or kept cold 36°F to 46°F (2°C to 8°C) when not in use.
- 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 space provided in this Pen User Manual.
- When carrying the pen away from home, store the pen in a way that keeps it cold 36°F to 46°F (2°C to 8°C) and dry.
- BYETTA should not be used after the expiration date printed on the label.
- Do not store the pen with the needle attached. If the needle is left on, 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.

Cleaning

- If needed, 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.



Questions and Answers

1. Do I need to do the New Pen Setup before every dose?

No. **The New Pen Setup is only done before each new pen is used for the first time.** The purpose of the setup is to check the flow of BYETTA from the tip of the needle. The small amount used in the New Pen Setup will not affect the 30-day supply of BYETTA. **If you repeat the New Pen Setup before each routine use, you will not receive 30 days of BYETTA from your pen.**

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 during New Pen Setup?

Carefully replace the outer needle shield and remove the needle. Attach a new needle, and repeat the instructions in New Pen Setup. If liquid is seen (stream or several drops), setup is complete.

4. Why is it hard to push the injection button in all the way?

The injection button may be hard to push because no needle is attached, the needle is not correctly attached, or because the needle is clogged.

Step 1) Attach a new needle. Make sure the needle is on straight and screwed on all the way.

Step 2) Hold pen with needle pointing up and push the injection button in all the way. Several drops or a tiny stream of BYETTA should come from the needle tip.

5. Why do I see BYETTA leaking from my needle after I inject?


A single drop may remain after injection is complete. This is normal.

If you see more than one drop:

- You may not have received your full dose. Do not inject another dose. Consult with your healthcare professional about how to handle a partial dose.
- To prevent this, for your next dose, make sure to **firmly push and hold** the injection button in and **slowly count to 5** (also see Step 8 of the Inject the Dose section on the other side of this Pen User Manual).

6. 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 maintaining pressure on the injection button with the needle still in your skin **and**
- the  is in the center of the dose window.


7. Why can't I pull, turn, or push the dose knob?


Check the symbol in the dose window and 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 won't turn, the cartridge in your BYETTA Pen may not have enough liquid to deliver a full dose. A small amount of BYETTA will always remain in the cartridge. If the cartridge contains a small amount or appears empty, obtain a new BYETTA Pen.

If  and part of the 10 are in the dose window and the dose knob can't be pushed in, the dose knob was not turned all the way. Continue turning until 10 clearly appears in the dose window.

If  is in the dose window and the dose knob won't turn, the injection button was not pushed in all the way and a complete dose was not delivered. Call your healthcare professional if you think you did not receive a complete dose. Follow these steps for your next injection:

Step 1) Hold the pen with needle up and firmly push the injection button in all the way until it stops. Continue applying pressure to injection button and slowly count to 5. Then turn the dose knob away from you (clockwise) until  appears in the dose window.

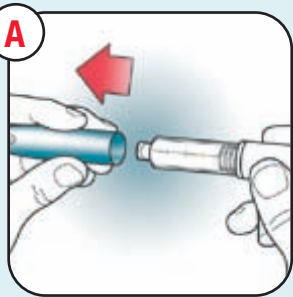
Step 2) If you cannot turn the dose knob, the needle may be clogged. Replace the needle and repeat Step 1 above.

Step 3) 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.

This Pen User Manual does not take the place of talking with your healthcare professional about your medical condition or your treatment. If you are having problems using your BYETTA Pen, call toll free 800-868-1190.

New Pen Setup

Read This before each new pen is used for the first time. Set up pen **only** at the start of its 30 days of use.

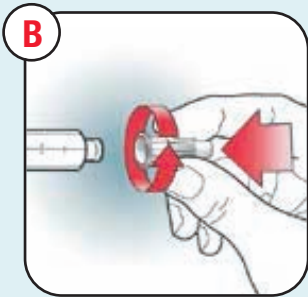


Wash hands prior to use.
Check pen label before each use to make sure it is your 10 mcg BYETTA Pen.

Pull off blue pen cap.

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

A small air bubble in the cartridge is normal.



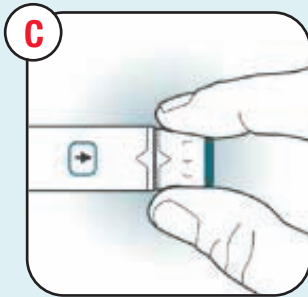
Remove paper tab from outer needle shield.

Push capped needle **straight** onto pen.

Screw needle on until secure.

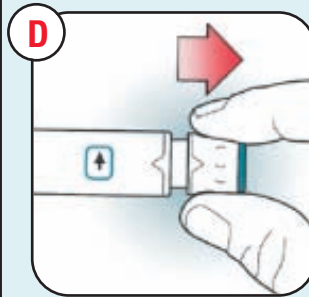
Pull off outer needle shield. **Do not** throw away.

Pull off inner needle shield and throw away.

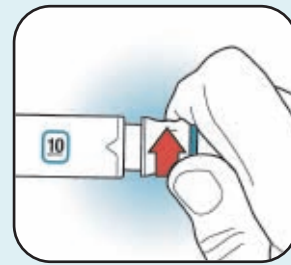


Check that is in dose window.

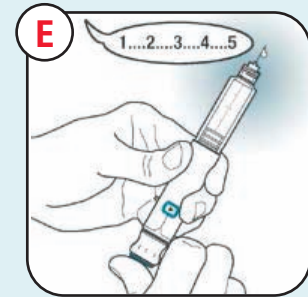
If not, turn dose knob away from you (clockwise) **until it stops** and is in dose window.



Pull dose knob out **until it stops** and is in dose window.



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



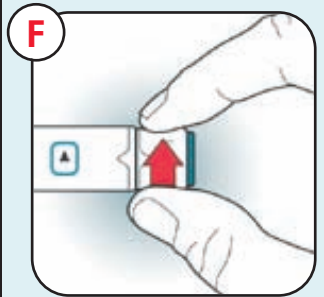
With needle pointing up,

- **firmly push** injection button in all the way **until it stops** and

- **keep holding injection button firmly** and

- **slowly count to 5.**

Watch for a stream or several drops. If none, repeat Steps C, D, and E up to three more times until a stream or several drops are seen. If BYETTA still does not come from needle tip, see **Questions and Answers**, number 3.

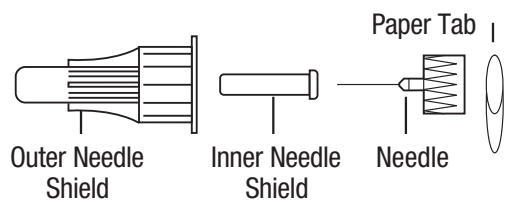


When is in the center of dose window, pen is ready to reset. Turn dose knob away from you **until it stops** and is in dose window.

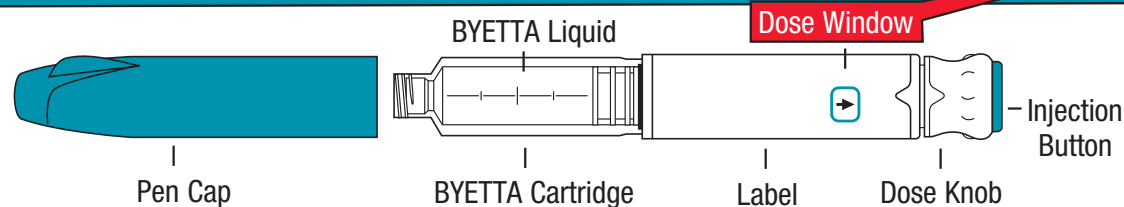
Go to **Dial the Dose** section below.

Important: Do not repeat New Pen Setup before each routine use or you will not receive 30 days of BYETTA from your pen.

Pen Needle Parts (Needles Not Included)



BYETTA Pen Parts



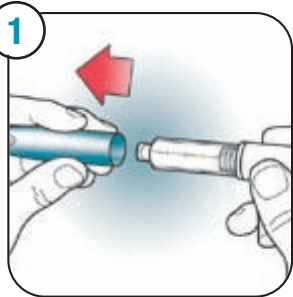
Dose Window Symbols

- ready to pull dose knob out
- ready to turn to dose position
- ready to inject 10 mcg
- dose knob in and ready to reset

Routine Use Follow these instructions for each routine injection.

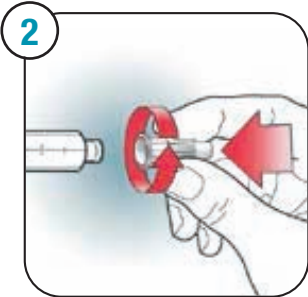
Attach the Needle

Check pen label before each use to make sure it is your 10 mcg BYETTA Pen. **Use a new needle for each injection.**



Wash hands prior to use.
Pull off blue pen cap and check BYETTA in the cartridge. The liquid should be clear, colorless, and free of particles. If not, do not use.

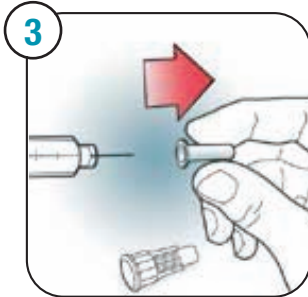
A small air bubble will not harm you or affect your dose.



Remove paper tab from outer needle shield.

Push capped needle **straight** onto pen.

Screw needle on until secure.

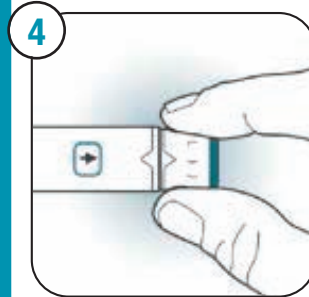


Pull off outer needle shield. **Do not** throw away.

Pull off inner needle shield and throw away.

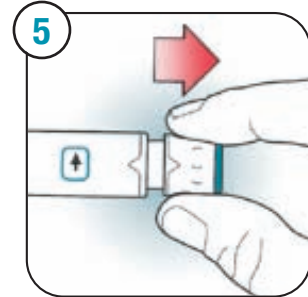
A small drop of liquid may appear. This is normal.

Dial the Dose

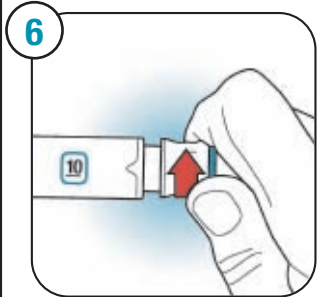


Check that is in dose window.

If not, turn dose knob away from you (clockwise) **until it stops** and is in dose window.



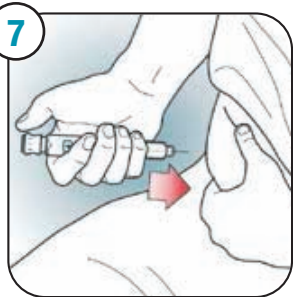
Pull dose knob out **until it stops** and is in dose window.



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

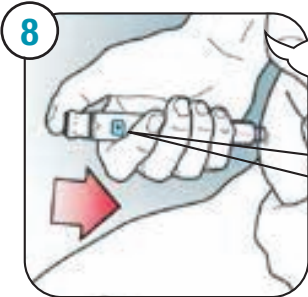
Note: If you cannot turn dose knob away from you to , see **Questions and Answers**, number 7.

Inject the Dose



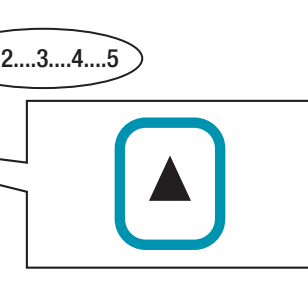
Grip the pen firmly in your hand.

Insert needle into skin using injection technique recommended by your healthcare professional.



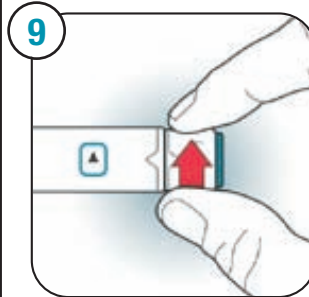
- Use thumb to **firmly push** injection button in all the way **until it stops** and
- **keep holding injection button firmly** and
- **slowly count to 5 to deliver full dose.**

Remove needle from skin.



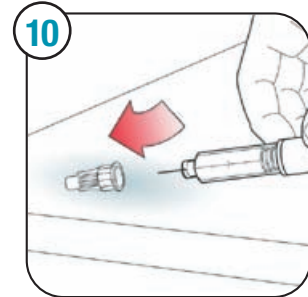
Injection is complete when is in the center of dose window.

If several drops of BYETTA are leaking from the needle, the injection button was not pushed in all the way. See **Questions and Answers**, number 5.



Reset the pen by turning dose knob away from you (clockwise) **until it stops** and is in dose window.

Note: If you cannot turn dose knob or your pen leaks, your full dose has not been delivered. See **Questions and Answers**, numbers 5 and 7.



Carefully replace outer needle shield.

Unscrew needle and place in a puncture-resistant container.

Note: Remove needle after each injection.

Replace blue cap on pen and **store in refrigerator.**

1st use date

____ / ____ / ____
Throw away 30 days after first use date,

OR

on expiration date printed on pen label, whichever date comes first.

Throw away date

____ / ____ / ____

For additional information, call toll free 800-868-1190 or visit www.BYETTA.com

Manufactured for Amylin Pharmaceuticals, Inc., San Diego, CA 92121
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Literature revised XXXX

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