

HumaPen LUXURA[®] HD

INSULIN DELIVERY DEVICE

INSTRUCTIONS FOR USE

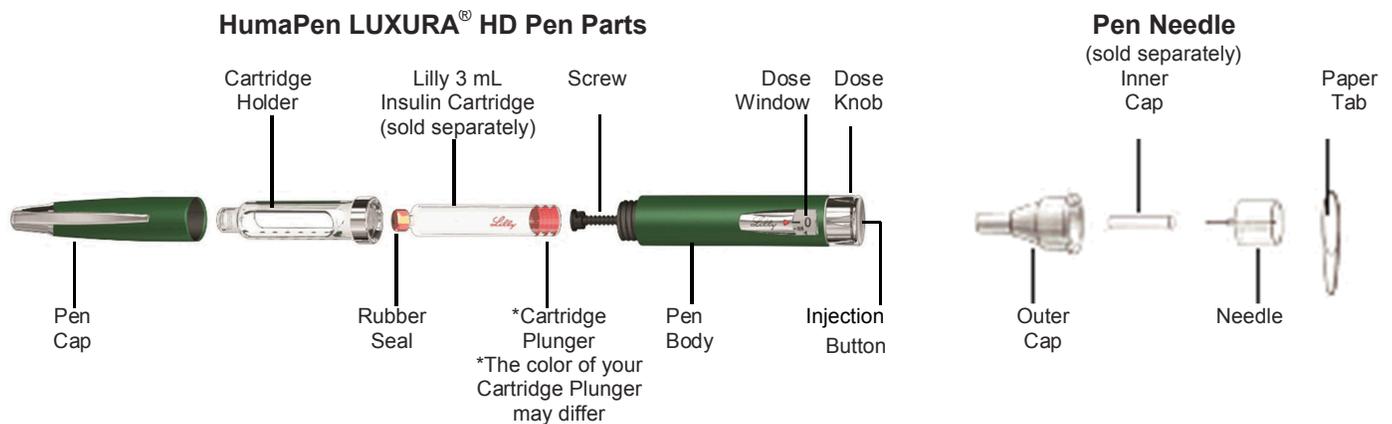
For use only with Lilly 3 mL insulin cartridges (100 units/mL). Do not use other brands of insulin cartridges.

The color of your HumaPen LUXURA[®] HD is Rainforest Green.

Rx only

For Single Patient Use Only.

Lilly



HumaPen LUXURA HD is designed for ease of use. You can give yourself multiple doses from one Lilly 3 mL insulin cartridge (100 units/mL). You can inject from 0.5 (1/2) to 30 units of insulin from a Lilly 3 mL insulin cartridge in each injection. You can dial your dose one-half (1/2) unit at a time. If you dial the wrong dose, you can correct the dose without wasting any insulin.

Read these instructions completely and follow the directions carefully before using the pen. Failure to follow the instructions may result in the wrong insulin dose being delivered.

DO NOT SHARE YOUR PEN OR NEEDLES AS INFECTION OR DISEASE CAN BE SPREAD FROM ONE PERSON TO ANOTHER.

If any of the parts of your Pen appear broken or damaged, DO NOT USE. Contact Lilly at 1-800-LillyRx (1-800-545-5979) or your healthcare provider for a replacement pen.

HumaPen LUXURA HD is not recommended for the blind or visually impaired without the assistance of a sighted individual trained to use it.

Always carry a spare insulin delivery device in case your pen is lost or damaged.

1 INSERT THE INSULIN CARTRIDGE

Important Notes

- Your healthcare provider has prescribed the type of insulin best for you. Any changes in insulin should be made only under medical supervision.

- HumaPen LUXURA HD is for use only with Lilly 3 mL insulin cartridges.
- **Do not use other brands of insulin cartridges.**
- Read and follow the instructions provided in your Lilly 3 mL insulin cartridge *Patient Information*.
- Before each injection, read the cartridge label and be sure the pen contains the correct Lilly 3 mL insulin cartridge.
- The color of the pen is not intended to indicate insulin type.
- The numbers on the cartridge holder give an estimate of the amount of insulin remaining in the cartridge. Do not use these numbers for measuring an insulin dose.
- For more information on HumaPen LUXURA HD and Lilly insulin, please refer to the *Patient Information* provided with your Insulin Cartridge or contact Lilly at 1-800-LillyRx (1-800-545-5979).

Frequently Asked Questions about Inserting the Insulin Cartridge

1. Why doesn't the screw move out when there is no cartridge in the pen?

The screw may not move out when you push the injection button unless there is a cartridge in the pen. This feature of the pen allows you to easily push the screw into the pen body when replacing a cartridge. Once a cartridge is inserted, the screw will move out when the injection button is pushed.

2. What should I do if I can't attach the cartridge holder to the pen body?

Check that the insulin cartridge is fully inserted into the cartridge holder. Then carefully line up the cartridge holder with the pen body and screw together until secure.

2 PRIME THE PEN (BEFORE EVERY INJECTION)

Important Notes

- HumaPen LUXURA HD is suitable for use with Becton, Dickinson and Company pen needles.
- The directions regarding needle handling are not intended to replace local, healthcare provider, or institutional policies.
- Use a new needle for each injection. This will help ensure sterility. It will also help prevent leakage of insulin, keep out air bubbles, and reduce needle clogs.

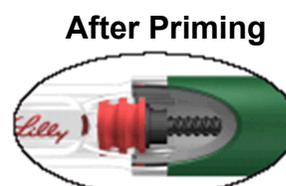
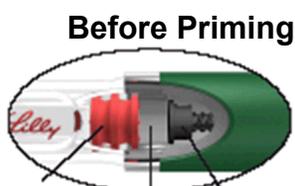
Frequently Asked Questions about Priming

1. Why is it important to prime before every injection?

If you do NOT prime, you may get the wrong insulin dose. Priming helps to ensure that the pen and needle are working properly. Once the pen is properly primed, insulin will flow from the needle. You may need to prime several times before you see insulin at the tip of the needle.

2. Why can it take several attempts to prime when a new cartridge is inserted?

There may be a gap between the screw and the cartridge plunger. Repeating the priming steps will move the screw out to touch the cartridge plunger. Once the end of the screw pushes the cartridge plunger out, insulin will flow from the needle.



*Cartridge Gap Screw
Plunger

No Gap Between Screw and Cartridge Plunger

*The color of your Cartridge Plunger may differ

- Repeat the priming steps until insulin is seen at the tip of the needle.
- If you are still unable to see insulin flow from the needle, go to Question 3.

3. Why should I prime until I see insulin at the tip of the needle?

Priming moves the screw into contact with the cartridge plunger and gets the air out of the cartridge.

- You may see insulin on the tip of the needle when you first attach it. This only shows that the needle is attached and not clogged. You must still prime the pen.
- You may also see no insulin at all when you are priming the pen. This may be because the screw is moving forward to close a gap between the screw and the cartridge plunger.
- Insulin will flow only when the pen is properly primed.
- If the injection button is hard to push, the needle may be clogged. Attach a new needle. Repeat the priming steps until insulin is seen at the tip of the needle.

If you are still unable to see insulin flow from the needle, **do NOT use** the pen. Contact Lilly at 1-800-LillyRx (1-800-545-5979) or your healthcare provider for assistance or to obtain a replacement.

4. What should I do if I have an air bubble in the cartridge?

Priming your pen will remove air. Point the pen up, and tap the cartridge gently with your finger so any air bubbles can collect near the top. Repeat the priming steps until insulin is seen at the tip of the needle. A small air bubble may remain in the cartridge after completion of the priming steps. If you have properly primed the pen, this small air bubble will not affect your insulin dose.

3 INJECT THE DOSE

Important Notes

- You must **PUSH** the injection button straight down for the dose to be delivered.
- You will **NOT** receive your insulin by turning the dose knob.
- Do not attempt to change the dose while injecting.

Frequently Asked Questions about Injecting

1. Why is it difficult to push the injection button when I try to inject?

- Your needle may be clogged. Try attaching a new needle, and then prime the pen.
- Pushing the injection button down quickly may make the button harder to push. Pushing the button more slowly may make it easier.
- Using a larger diameter needle will make it easier to push the injection button during injection. Ask your healthcare provider which needle is best for you.
- Your injection button may become harder to push if the inside of your pen gets dirty with insulin, food, drink or other materials. Following the CARE AND STORAGE instructions below should prevent this.

If none of the above steps resolves the problem, your pen may need to be replaced.

2. Why doesn't the dose knob go to zero when I inject my dose?

This can happen if the insulin cartridge does not have enough insulin left in it for your entire dose. The number in the dose window is the amount you did **NOT receive**. To get the rest of your dose, remove the needle, change the insulin cartridge, attach a new needle, and prime the pen. Then complete your dose by dialing the amount that you did **NOT receive** and inject only this amount.

CARE AND STORAGE

- Remove the needle after every use. Do not store the pen with the needle attached.
- Keep your HumaPen LUXURA HD, Lilly 3 mL insulin cartridges, and needles out of the reach and sight of children.
- Keep the pen away from moisture, dust, extreme hot or cold temperatures, and direct sunlight.
- Do not store the pen in a refrigerator.
- Wipe the pen cap, pen body, and case with a damp cloth to clean them.
- Do not use alcohol, hydrogen peroxide, or bleach on the pen body or dose window. Also, do not cover in liquid or apply lubrication such as oil, as this could damage the pen.
- Refer to the insulin cartridge *accompanying literature* for complete insulin storage instructions.

REPLACEMENT

Your HumaPen LUXURA HD has been designed to be used for up to 3 years after first use. Record the date your Pen was first used here: __/__/__. Contact your healthcare provider to get a prescription for a new HumaPen LUXURA HD when your Pen has been used for 3 years. If you have any questions or problems with your HumaPen LUXURA HD, contact Lilly at 1-800-LillyRx (1-800-545-5979) or your healthcare provider for assistance.

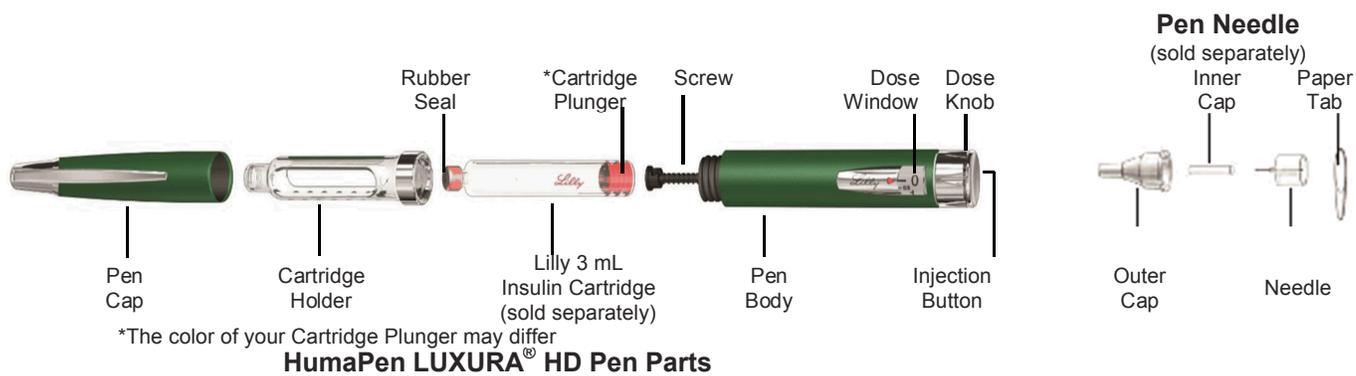
The Lilly logo is written in a red, cursive script font.

Getting Ready

Wash your hands and make sure you have the following items before beginning:

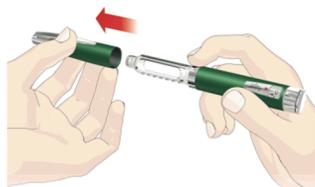
- HumaPen LUXURA[®] HD
- Lilly 3 mL insulin cartridge
- New pen needle
- Alcohol swab

HumaPen LUXURA[®] HD INSULIN DELIVERY DEVICE



1 INSERT THE INSULIN CARTRIDGE

Pull Off Pen Cap

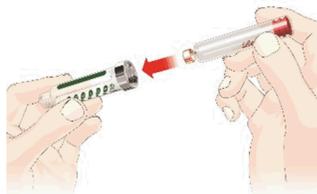


Unscrew Cartridge Holder



A

Insert Cartridge



Insert small end of Lilly 3 mL insulin cartridge into the cartridge holder.

Note:

Check the insulin cartridge to make sure it is not cracked or broken and your insulin is not expired before inserting the insulin cartridge.

B

Push Screw Back



- The screw may be in or out when you get the pen.
- If the screw is out, use the cartridge plunger to push the screw back.

Note:

If you push the injection button without a cartridge in the cartridge holder the screw will not move forward.

C

Attach Cartridge Holder



Push the cartridge holder and pen body straight together. Screw the pen body onto the cartridge holder until it is secure.

⚠ Caution: If the cartridge holder is not completely attached, the screw may not move and you may not get your full dose.

D

Inspect Insulin



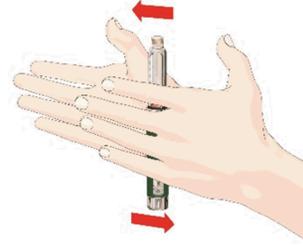
Be sure to check your insulin for:

- Type
- Appearance

Wipe the small rubber seal on the end of the cartridge with an alcohol swab.

E

For Cloudy Insulin Only



Roll the pen gently 10 times,



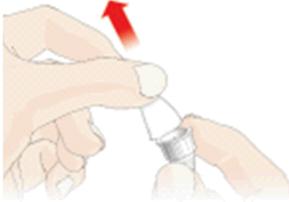
and invert the pen 10 times. The insulin should look evenly mixed.

F

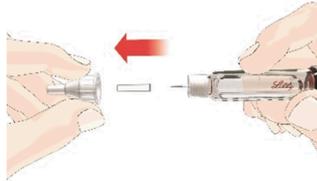
2 PRIME THE PEN (BEFORE EVERY INJECTION)

⚠ Caution: If you do **NOT** prime, you may get the wrong insulin dose.

Remove Paper Tab



Remove Needle Cap



Dial 2 Units



Attach Needle



Screw needle **straight** onto the cartridge holder.

A

Pull off the outer cap. Save the outer cap to remove the needle after your injection.

Pull off the inner cap and throw it away.

B

Tap Cartridge

Point pen up.

Tap cartridge to collect air at the top for removal.



C

Prime The Pen



Push injection button and hold for 5 seconds.

Look for insulin at the tip of the needle.

If No Insulin Is Seen, Repeat Priming

Dial 2 units.



Tap cartridge.



Caution: If no insulin flows after several attempts, attach a new needle, as the one on your pen may be clogged. A new cartridge may need to be primed several times to get a drop of insulin.

Push injection button and look for **insulin at the needle tip.**



D

E

3 INJECT THE DOSE

Dial Your Dose



Turn dose knob to your desired dose.

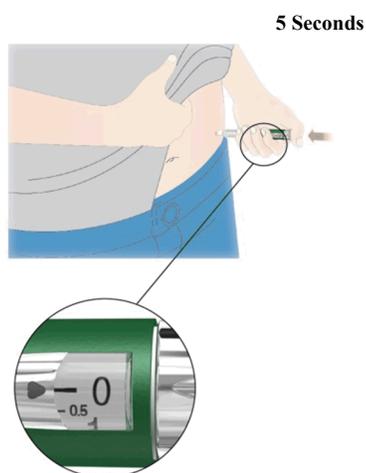
Example: 5.5 (5½) units shown in the drawing above.

If you dial too many units, you can correct the dose by dialing backwards.

The dose knob clicks as you turn it. **DO NOT** dial your dose by counting clicks because you may dial the wrong dose.

A

Inject Your Dose



Insert the needle as directed by your healthcare provider.

Place your thumb on the injection button then **slowly** and firmly push the button until it stops moving.



Continue to hold the button for **5 seconds**, then remove the needle from your skin.

Check to make sure you see a **0** in the dose window to confirm you received the complete dose.

Note:

It is possible to set a dose larger than the amount of insulin left in the cartridge.

At the end of an injection, the number in the dose window should be **0**. If it is not, this is the amount of insulin you did **NOT receive**.

Remember this number.

Remove the needle and the empty cartridge.

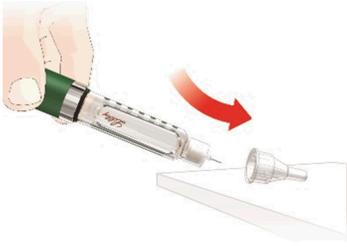
Insert a new cartridge as shown in 1, attach a new needle, and prime the pen as shown in 2.

Complete your dose by injecting only the amount you did not receive.

If you do not think you received your full dose, do not take another dose.

Call Lilly at 1-800-LillyRx (1-800-545-5979) or your healthcare provider for assistance.

Replace Needle Outer Cap



Carefully replace the outer cap as instructed by your healthcare provider.

Note:

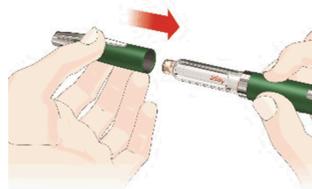
To prevent air from entering the cartridge, do not store the pen with a needle attached.

Remove The Needle



- Remove the capped needle by twisting it off.
- Put used needles in a sharps container or a hard plastic container with a secure lid. Do not throw needles directly into your household trash.
- Do not recycle the filled container. The full container must be disposed of according to your state and local laws.
- For information on how to dispose of the container properly, ask your healthcare provider about options available in your area or go to the FDA website at: www.fda.gov/safesharpsdisposal.

Replace Pen Cap



C

D

If you have any questions or problems with your HumaPen LUXURA HD, contact Lilly at 1-800-LillyRx (1-800-545-5979) or your healthcare provider for assistance.



Manufacturer:
Eli Lilly and Company
Pharmaceutical Delivery Systems
Lilly Corporate Center
Indianapolis, IN 46285, USA

HumaPen LUXURA HD meets the dose accuracy and functional requirements of ISO 11608-1:2000 with Lilly 3 mL cartridges.

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The Lilly logo, featuring the word "Lilly" in a red, cursive script font.