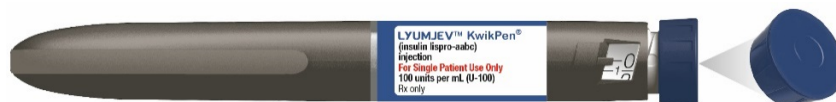


Instructions for Use
LYUMJEV™ KwikPen® (LOOM-jehv)
(insulin lispro-aabc)
injection, for subcutaneous use
3 mL single-patient-use pen
100 units/mL



Lilly

Read the Instructions for Use before you start taking LYUMJEV™ and each time you get another LYUMJEV KwikPen. 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.

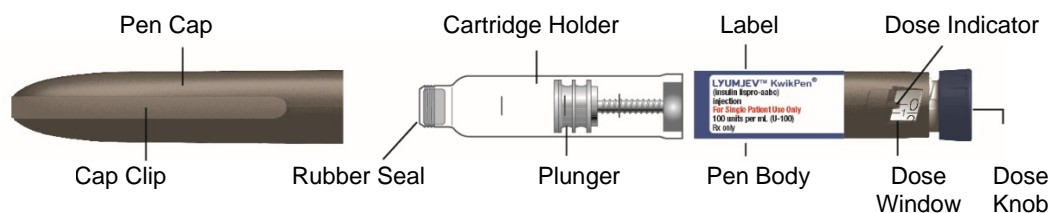
Do not share your LYUMJEV KwikPen with other people, even if the needle has been changed. Do not reuse or share needles with other people. You may give other people a serious infection or get a serious infection from them.

LYUMJEV KwikPen (“Pen”) is a disposable single-patient-use prefilled pen containing 300 units of LYUMJEV.

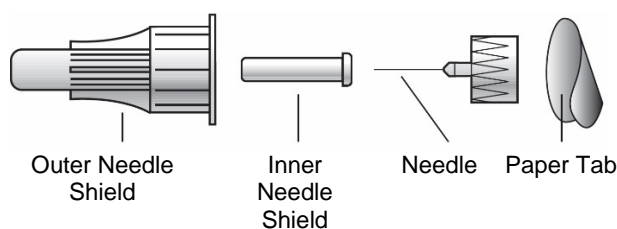
- Your healthcare provider will tell you how many units to give as your dose and how to inject your prescribed dose of insulin.
- You can give yourself more than 1 dose from the Pen.
- Each turn of the dose knob dials 1 unit of insulin. You can give from 1 to 60 units in a single injection.
- If your dose is more than 60 units, you will need to give yourself more than 1 injection. Always check the number in the dose window to make sure you dialed the correct dose.
- The plunger only moves a little with each injection, and you may not notice that it moves. The plunger will only reach the end of the cartridge when you have used all 300 units in the Pen.

People who are blind or have vision problems should not use the Pen without help from a person trained to use the Pen.

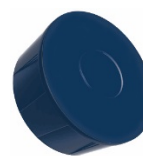
LYUMJEV KwikPen Parts



Pen Needle Parts (Needles Not Included)



Dose Knob



How to recognize your LYUMJEV KwikPen

- Pen color: Taupe
- Dose Knob: Blue, with raised ridges on side
- Label: Blue and white

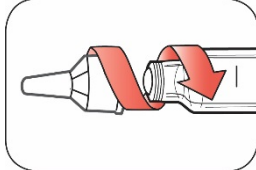
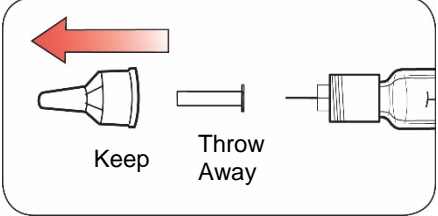
Supplies needed to give your injection

- LYUMJEV KwikPen, 100 units/mL
- KwikPen compatible needle (Becton, Dickinson and Company Pen needles recommended)
- Alcohol swab
- Gauze (optional)

Preparing your Pen

- Wash your hands with soap and water.
- Check the Pen to make sure you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.
- **Do not** use your Pen past the expiration date printed on the label or for more than 28 days after you first start using the Pen.
- Always use a **new needle** for each injection to help prevent infections and blocked needles.

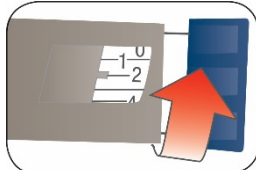

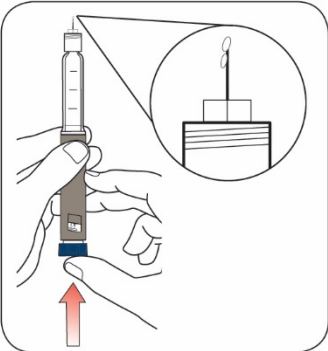
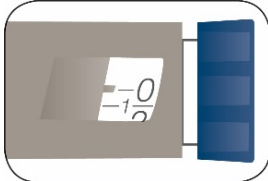
| | |
|---|---|
| <p>Step 1:</p> <ul style="list-style-type: none"> • Pull the Pen cap straight off. <ul style="list-style-type: none"> – Do not remove the Pen label. • Wipe the rubber seal with an alcohol swab. | <p>The illustration shows a hand pulling the grey pen cap straight off the top of the pen. A red arrow points to the left, indicating the direction of removal.</p> |
| <p>Step 2:</p> <ul style="list-style-type: none"> • Check the liquid in the Pen. • LYUMJEV should look clear and colorless. Do not use if it is cloudy, colored, or has particles or clumps in it. | <p>The illustration shows a hand holding the pen and looking into the clear window to inspect the liquid inside.</p> |
| <p>Step 3:</p> <ul style="list-style-type: none"> • Select a new needle. • Pull off the paper tab from the outer needle shield. | <p>The illustration shows a hand pulling the paper tab away from the outer needle shield. A red arrow points upwards, indicating the direction of removal.</p> |

| | |
|---|---|
| <p>Step 4:</p> <ul style="list-style-type: none"> • Push the capped needle straight onto the Pen and twist the needle on until it is tight. |  |
| <p>Step 5:</p> <ul style="list-style-type: none"> • Pull off the outer needle shield. Do not throw it away. • Pull off the inner needle shield and throw it away. |  |

Priming your Pen

Prime before each injection.

- Priming your Pen means removing the air from the needle and cartridge that may collect during normal use and ensures that your Pen is working correctly.
- If you **do not** prime before each injection, you may get too much or too little insulin.

| | |
|--|---|
| <p>Step 6:</p> <ul style="list-style-type: none"> • To prime your Pen, turn the dose knob to select 2 units. |  |
| <p>Step 7:</p> <ul style="list-style-type: none"> • Hold your Pen with the needle pointing up. Tap the cartridge holder gently to collect air bubbles at the top. |  |
| <p>Step 8:</p> <ul style="list-style-type: none"> • Continue holding your Pen with the needle pointing up. Push the dose knob in until it stops and “0” is seen in the dose window. Hold the dose knob in and count to 5 slowly. <p>You should see insulin at the tip of the needle.</p> <ul style="list-style-type: none"> – If you do not see insulin, repeat priming steps 6 to 8, but not more than 4 times. – If you still do not see insulin, change the needle and repeat priming steps 6 to 8. <p>Small air bubbles are normal and will not affect your dose.</p> |   |

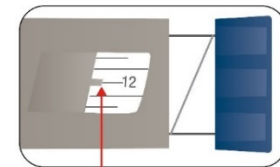
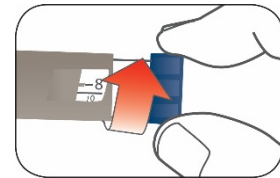
Selecting your dose

- You can give from 1 to 60 units in a single injection.

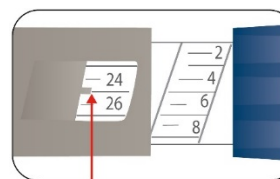
- If your dose is more than 60 units, you will need to give more than 1 injection.
 - If you need help with dividing up your dose the right way, ask your healthcare provider.
 - Use a new needle for each injection and repeat the priming steps.

Step 9:

- Turn the dose knob to select the number of units you need to inject. The dose indicator should line up with your dose.
 - The Pen dials 1 unit at a time.
 - The dose knob clicks as you turn it.
 - **Do not** dial your dose by counting the clicks. You may dial the wrong dose. This may lead to you getting too much insulin or not enough insulin.
 - The dose can be corrected by turning the dose knob in either direction until the correct dose lines up with the dose indicator.
 - The **even** numbers are printed on the dial. The example to the right shows 12 units in the dose window.
 - The **odd** numbers, after the number 1, are shown as full lines between the numbers. The example to the right shows 25 units in the dose window.
- **Always check the number in the dose window to make sure you have dialed the correct dose.**



Example: 12 units shown in the dose window



Example: 25 units shown in the dose window

- The Pen will not let you dial more than the number of units left in the Pen.
- If you need to inject more than the number of units left in the Pen, you may either:
 - inject the amount left in your Pen and then use a new Pen to give the rest of your dose,

or

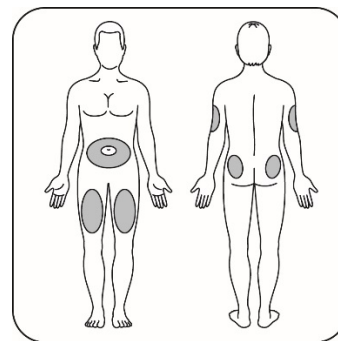
 - get a new Pen and inject the full dose.
- It is normal to see a small amount of insulin left in the Pen that you cannot inject.

Giving your injection

- Inject your insulin as your healthcare provider has shown you.
- Change (rotate) your injection sites within the area you choose for each dose to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the injection sites.
- **Do not** use the exact same spot for each injection.
- **Do not** inject where the skin has pits, is thickened, or has lumps.
- **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
- **Do not** try to change your dose while injecting.

Step 10:

- Choose your injection site.
LYUMJEV is injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs or upper arms.
- Wipe your skin with an alcohol swab, and let your skin dry before you inject your dose.

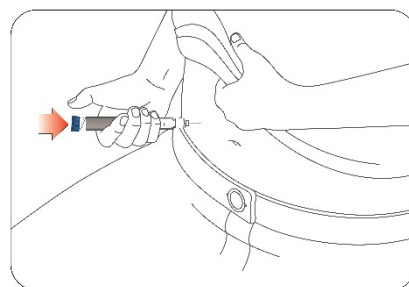


Step 11:

- Insert the needle into your skin.
- Push the dose knob all the way in.
- Continue to hold the dose knob in and **slowly count to 5** before removing the needle.

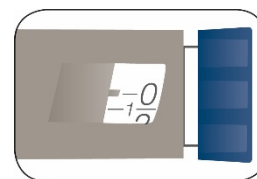


Do not try to inject your insulin by turning the dose knob. You will **not** receive your insulin by turning the dose knob.



Step 12:

- Pull the needle out of your skin.
 - A drop of insulin at the needle tip is normal. It will not affect your dose.
- Check the number in the dose window.
 - If you see “0” in the dose window, you have received the full amount you dialed.
 - If you do not see “0” in the dose window, you did not receive your full dose. **Do not** redial. Insert the needle into your skin and finish your injection.
 - If you **still** do not think you received the full amount you dialed for your injection, **do not start over or repeat that injection**. Monitor your blood glucose as instructed by your healthcare provider.
 - If you normally need to give 2 injections for your full dose, be sure to give your second injection.

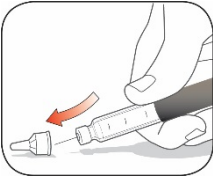
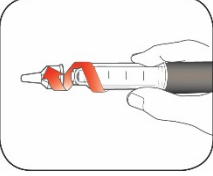



The plunger only moves a little with each injection, and you may not notice that it moves.

If you see blood after you take the needle out of your skin, press the injection site lightly with a piece of gauze or an alcohol swab.

Do not rub the area.

After your injection

| | |
|---|---|
| <p>Step 13:</p> <ul style="list-style-type: none">Carefully replace the outer needle shield. |  |
| <p>Step 14:</p> <ul style="list-style-type: none">Unscrew the capped needle and throw it away (see Disposing of Pens and needles section).Do not store the Pen with the needle attached to prevent leaking, blocking the needle, and air from entering the Pen. |  |
| <p>Step 15:</p> <ul style="list-style-type: none">Replace the Pen cap by lining up the cap clip with the dose indicator and pushing straight on. |  <p>Cap Clip</p> |

Disposing of Pens and needles

- Put your used needles in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles 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. 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>
- Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.
- The used Pen may be discarded in your household trash after you have removed the needle.

Storing your Pen

Unused Pens

- Store unused Pens in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Do not** freeze LYUMJEV. **Do not** use if it has been frozen.
- Unused Pens may be used until the expiration date printed on the label if the Pen has been kept in the refrigerator.

In-use Pen

- Store the Pen you are currently using at room temperature [up to 86°F (30°C)]. Keep away from heat and light.
- Throw away the LYUMJEV KwikPen you are using after 28 days, even if it still has insulin left in it.

General information about the safe and effective use of your Pen

- Keep your Pen and needles out of the sight and reach of children.**

- **Do not** use your Pen if any part looks broken or damaged.
- Always carry an extra Pen in case yours is lost or damaged.

Troubleshooting

- If you cannot remove the Pen cap, gently twist the cap back and forth, and then pull the cap straight off.
- If the dose knob is hard to push:
 - pushing the dose knob more slowly will make it easier to inject.
 - your needle may be blocked. Put on a new needle and prime the Pen.
 - you may have dust, food, or liquid inside the Pen. Throw the Pen away and get a new Pen.

If you have any questions or problems with your LYUMJEV KwikPen, contact Lilly at 1-800-545-5979 or call your healthcare provider for help. For more information on LYUMJEV KwikPen and insulin, go to www.lyumjev.com.



Scan this code to launch
www.lyumjev.com

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

Manufactured by:
Eli Lilly and Company
Indianapolis, IN 46285, USA
US License Number 1891

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LYUMJEV KwikPen meets the current dose accuracy and functional requirements of ISO 11608-1.

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