

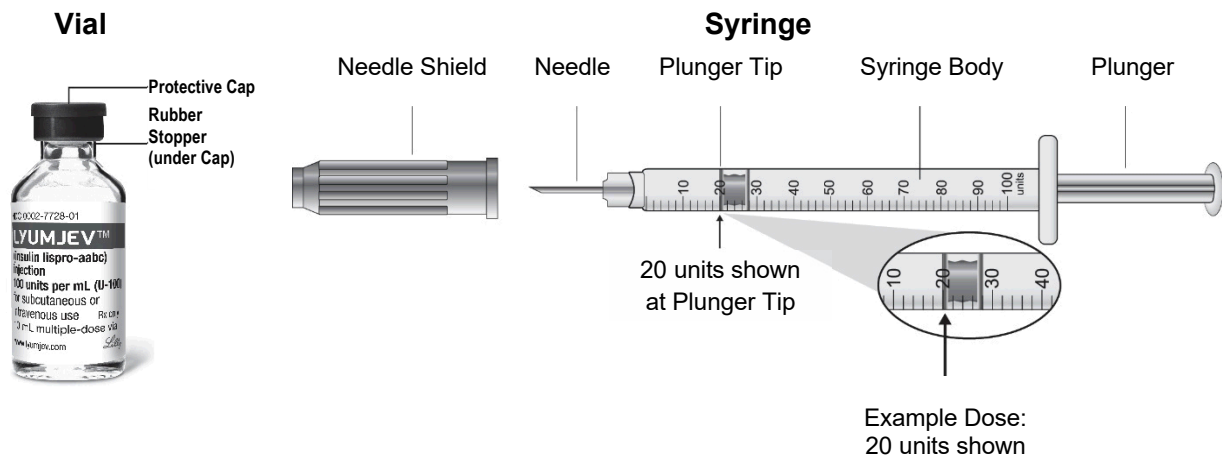
Instructions for Use
LYUMJEV™ (LOOM-jehv)
(insulin lispro-aabc) injection
for subcutaneous use
(100 units/mL, 10 mL multiple-dose vial)

Read the Instructions for Use before you start taking LYUMJEV and each time you get a new vial. 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 syringes or needles with other people. You may give other people a serious infection or get a serious infection from them.



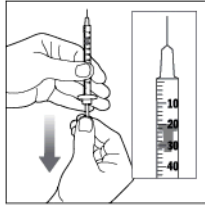
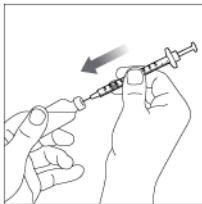
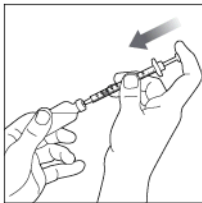
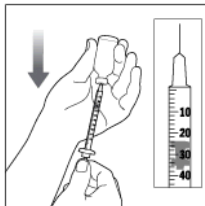

Supplies needed to give your injection

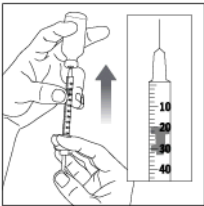

- a multiple-dose LYUMJEV vial
- a U-100 insulin syringe and needle (Becton, Dickinson and Company syringes and needles recommended)
- 2 alcohol swabs
- gauze (optional)
- 1 sharps container for throwing away used syringes and needles. See “**Disposing of used syringes and needles**” at the end of these instructions.



Preparing your LYUMJEV dose

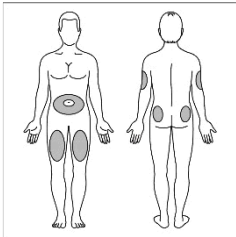

- Wash your hands with soap and water.
- Check the LYUMJEV label to make sure you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.
- LYUMJEV should look clear and colorless. **Do not** use LYUMJEV if it is thick, cloudy, or colored, or if you see lumps or particles in it.
- **Do not** use LYUMJEV past the expiration date printed on the label or 28 days after you first use it.
- **Always use a new syringe and needle for each injection to prevent infections and blocked needles.**
- **Do not** mix LYUMJEV U-100 with other insulins.


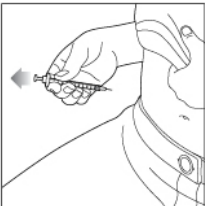
<p>Step 1:</p> <p>If you are using a new vial, pull off the plastic protective cap, but do not remove the rubber stopper.</p>	
<p>Step 2:</p> <p>Wipe the rubber stopper with an alcohol swab.</p>	
<p>Step 3:</p> <p>Remove the needle shield from the syringe by pulling the needle shield straight off. Hold the syringe with the needle pointing up. Pull down on the plunger until the plunger tip reaches the line for the number of units for your prescribed dose.</p>	 <p>(Example Dose: 20 units shown)</p>
<p>Step 4:</p> <p>Push the needle through the rubber stopper of the vial.</p>	
<p>Step 5:</p> <p>Push the plunger all the way in. This puts air into the vial.</p>	
<p>Step 6:</p> <p>Turn the vial and syringe upside down and slowly pull the plunger down until the plunger tip is a few units past the line for your prescribed dose.</p> <p>If there are air bubbles, tap the syringe gently a few times to let any air bubbles rise to the top.</p>	 <p>(Example Dose: 20 units, plunger is shown at 24 units)</p> 

<p>Step 7:</p> <p>Slowly push the plunger up until the plunger tip reaches the line for your prescribed dose.</p> <p>Check the syringe to make sure that you have the right dose.</p>	 <p>(Example Dose: 20 units shown)</p>
<p>Step 8:</p> <p>Pull the syringe out of the rubber stopper of the vial.</p>	

Giving your LYUMJEV injection with a syringe

- Inject your insulin exactly as your healthcare provider has shown you. Your healthcare provider should tell you if you should pinch the skin before injecting.
- LYUMJEV **starts acting fast**, so give your injection at the start of a meal or within 20 minutes after you start a meal.
- 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.

<p>Step 9:</p> <p>Choose your injection site.</p> <p>LYUMJEV is injected under the skin (subcutaneously) of your stomach area (abdomen), buttocks, upper legs, or upper arms.</p> <p>Wipe your skin with an alcohol swab, and let your skin dry before you inject your dose.</p>	
<p>Step 10:</p> <p>Insert the needle into your skin.</p>	

<p>Step 11:</p> <p>Push down on the plunger to inject your dose.</p> <p>The needle should stay in your skin for at least 5 seconds after pushing down on the plunger to make sure you have injected all of your insulin dose.</p>	
<p>Step 12:</p> <p>Pull the needle out of your skin.</p> <ul style="list-style-type: none"> • If you see blood after you take the needle out of your skin, press the injection site with a piece of gauze or an alcohol swab. Do not rub the area. • Do not recap the needle. Recapping the needle can lead to a needle stick injury. 	

Giving your LYUMJEV using an insulin pump

- If you have been prescribed an insulin pump, check the pump manufacturer's user manual to see if LYUMJEV can be used with the pump.
- LYUMJEV should be given into an area of your body recommended in the instructions that come with your insulin pump.
- Change LYUMJEV in the pump reservoir at least every 9 days or according to the pump user manual, whichever is shorter, even if you have not used all of the insulin.
- Change (rotate) your insertion sites within the area you choose for each insertion to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the insertion sites. **Do not** insert into the exact same spot for each insertion. **Do not** insert where the skin has pits, is thickened, or has lumps. **Do not** insert where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
- Call your healthcare provider and choose a new infusion site if the skin at the infusion site becomes red, itchy, or thickened.
- Your healthcare provider should provide recommendations for appropriate pump basal and meal-time infusion rates. Call your healthcare provider if you have any questions about using the insulin pump.
- **Do not** dilute or mix LYUMJEV with any other type of insulin in your insulin pump.
- You should be trained on how to give insulin by injection and have an alternative insulin delivery system in case of pump failure.

Disposing of used syringes and needles

- Put your used syringes and needles in a FDA-cleared sharps disposal container right away after use. **Do not throw away (dispose of) loose syringes and 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 syringes and needles. 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.

How should I store LYUMJEV?

All not in-use (unopened) vials:

- Store all not in-use (unopened) vials in the refrigerator at 36°F to 46°F (2°C to 8°C).
- **Do not freeze. Do not use** if LYUMJEV has been frozen.
- Keep away from direct heat and light.
- Not in-use (unopened) vials can be used until the expiration date on the carton and label, if they have been stored in the refrigerator.
- Not in-use (unopened) vials should be thrown away after 28 days, if they are stored at room temperature.

After vials have been in-use (opened):

- Store in-use (opened) vials in the refrigerator or at room temperature below 86°F (30°C) for up to 28 days.
- Keep vials away from direct heat and light.
- Throw away all in-use (opened) vials after 28 days of use, even if there is insulin left in the vial.

LYUMJEV in an insulin pump:

- Throw away LYUMJEV in the pump reservoir if it has been exposed to temperatures higher than 98.6°F (37°C).

Keep LYUMJEV vials, syringes, needles and all medicines out of the sight and reach of children.

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



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www.lyumjev.com

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

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

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