

Patient Information

LYUMJEV® (LOOM-jehv) (insulin lispro-aabc) injection, for subcutaneous or intravenous use

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

What is LYUMJEV?

- LYUMJEV is a man-made fast-acting insulin used to control high blood sugar in adults and children with diabetes mellitus.

Do not take LYUMJEV if you:

- are having an episode of low blood sugar (hypoglycemia).
- have an allergy to insulin lispro-aabc or any of the ingredients in LYUMJEV. See the end of this Patient Information leaflet for a complete list of ingredients in LYUMJEV.

Before taking LYUMJEV, tell your healthcare provider about all of your medical conditions, including if you:

- have kidney or liver problems.
- take any other medicines, especially ones called thiazolidinediones (TZDs).
- have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs with LYUMJEV.
- are pregnant or plan to become pregnant. Talk with your healthcare provider about the best way to control your blood sugar if you plan to become pregnant or while you are pregnant.
- are breastfeeding or plan to breastfeed. It is not known if LYUMJEV passes into your breast milk. You and your healthcare provider should decide if you will take LYUMJEV while you breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

Before you start taking LYUMJEV, talk to your healthcare provider about low blood sugar and how to manage it.

How should I take LYUMJEV?

- Read the **Instructions for Use** that come with your LYUMJEV.
- Take LYUMJEV exactly as your healthcare provider tells you to. Your healthcare provider will tell you how much LYUMJEV to take and when to take it.
- **LYUMJEV starts acting fast.** Inject LYUMJEV at the beginning of a meal or within 20 minutes after you start eating a meal.
- Know the type and strength of insulin you take. **Do not** change the type or amount of insulin you take unless your healthcare provider tells you to. The amount of insulin and the best time for you to take your insulin may need to change if you take different types of insulin.
- Check your insulin label each time you give your injection to make sure you are using the correct insulin.
- **Check your blood sugar levels.** Ask your healthcare provider what your blood sugars should be and when you should check your blood sugar level.
- LYUMJEV comes in U-100 (100 units/mL) and U-200 (200 units/mL) insulin strengths. LYUMJEV U-200 contains 2 times as much insulin (200 units/mL) in 1 mL as LYUMJEV U-100 (100 units/mL).
- LYUMJEV U-100 and LYUMJEV U-200 can be injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs, or upper arms.
- LYUMJEV U-100 can be given by continuous infusion under the skin (subcutaneously) through an insulin pump into an area of your body recommended in the instructions that come with your insulin pump. LYUMJEV U-200 **cannot** be given through an insulin pump.
- LYUMJEV U-100 can also be given in your vein (intravenously) by your healthcare provider. LYUMJEV U-200 **cannot** be given in your vein.
- **Change (rotate) your injection sites within the area you choose with each dose** to reduce your risk of getting pits in skin or thickened skin (lipodystrophy) and skin with lumps (localized cutaneous amyloidosis) at the injection sites.
 - o **Do not** use the exact same spot for each injection.
 - o **Do not** inject where the skin has pits, is thickened, or has lumps.
 - o **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
- If you miss a dose of LYUMJEV, monitor your blood sugar levels to decide if an insulin dose is needed. Continue with your regular dosing schedule at the next meal.

- LYUMJEV comes in a vial, single-patient-use prefilled pen, or in a cartridge. **Do not** use a syringe to remove LYUMJEV from your single-patient-use prefilled pen or cartridge.

Keep LYUMJEV and all medicines out of the reach of children.

Your dose of LYUMJEV may need to change because of:

a change in level of physical activity or exercise, weight gain or loss, increased stress, illness, change in diet, or because of other medicines you take.

What should I avoid while taking LYUMJEV?

While taking LYUMJEV do not:

- drive or operate heavy machinery, until you know how LYUMJEV affects you.
- drink alcohol or take other medicines that contain alcohol.

What are the possible side effects of LYUMJEV?

LYUMJEV may cause serious side effects that can lead to death, including:

- **low blood sugar (hypoglycemia).** Signs and symptoms that may indicate low blood sugar include: dizziness or light-headedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, hunger, anxiety, irritability, or mood changes.
- **low potassium in your blood (hypokalemia).**
- **serious allergic reactions (whole body allergic reaction).** **Get emergency medical help right away, if you have any of these symptoms of a severe allergic reaction:** a rash over your whole body, trouble breathing, a fast heartbeat, swelling of your face, tongue, or throat, sweating, or feeling faint.
- **heart failure.** Taking certain diabetes pills called thiazolidinediones (TZDs) with LYUMJEV may cause heart failure in some people. This can happen even if you have never had heart failure or heart failure problems before. If you already have heart failure it may get worse while you take TZDs with LYUMJEV. Your healthcare provider should monitor you closely while you are taking TZDs with LYUMJEV. Tell your healthcare provider if you have any new or worse symptoms of heart failure including: shortness of breath, swelling of your ankles or feet, or sudden weight gain. Treatment with TZDs and LYUMJEV may need to be adjusted or stopped by your healthcare provider if you have new or worse heart failure.
- **sudden onset of high blood sugar (hyperglycemia) and high amounts of ketones in the blood or urine (ketoacidosis) due to insulin pump problems.** If LYUMJEV is given through an insulin pump and the pump is not working the right way or in case of handling errors, you may not get the right amount of insulin, which can cause a sudden onset of high blood sugar and high amounts of ketones in the blood or urine.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, swelling of your face, tongue or throat, sweating, extreme drowsiness, dizziness, or confusion.

The most common side effects of LYUMJEV include:

- low blood sugar (hypoglycemia)
- allergic reactions
- rash
- itching (pruritus)
- reactions or pain at the site of injection or at the site of infusion with insulin pump use (treprostinil sodium and sodium citrate dihydrate are inactive ingredients in LYUMJEV that have been known to cause reactions and pain at the infusion and injection sites in other non-insulin medicines)
- thickening or pits at the injection or infusion site (lipodystrophy)
- weight gain

These are not all the possible side effects of LYUMJEV. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of LYUMJEV.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not take LYUMJEV for a condition for which it was not prescribed. **Do not** give LYUMJEV to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about LYUMJEV that is written for health professionals.

What are the ingredients in LYUMJEV?

Active ingredient: insulin lispro-aabc

Inactive ingredients: glycerol, magnesium chloride hexahydrate, metacresol, sodium citrate dihydrate, treprostinil sodium, zinc oxide (zinc ion), and Water for Injection, USP

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For more information, go to www.lilly.com or call 1-800-545-5979.

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