Patient Information
Insulin Lispro Injection
U-100 (100 units per mL)
for subcutaneous or intravenous use

Do not share your Insulin Lispro Injection prefilled pens or syringes 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 Insulin Lispro Injection?
• Insulin Lispro Injection is a man-made fast-acting insulin used to control high blood sugar in adults and children with diabetes mellitus.
• It is not known if Insulin Lispro Injection is safe and effective in children younger than 3 years of age or when used to treat children with type 2 diabetes mellitus.

Who should not take Insulin Lispro Injection?
Do not take Insulin Lispro Injection if you:
• are having an episode of low blood sugar (hypoglycemia).
• have an allergy to Insulin Lispro Injection or any of the ingredients in Insulin Lispro Injection. See the end of this Patient Information leaflet for a complete list of ingredients in Insulin Lispro Injection.

What should I tell my healthcare provider before taking Insulin Lispro Injection?
Before taking Insulin Lispro Injection, 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 TZDs (thiazolidinediones).
• have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs with Insulin Lispro Injection.
• 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. Talk with your healthcare provider about the best way to feed your baby while taking Insulin Lispro Injection.

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 Insulin Lispro Injection, talk to your healthcare provider about low blood sugar and how to manage it.

How should I take Insulin Lispro Injection?
• Read the Instructions for Use that comes with your Insulin Lispro Injection.
• Take Insulin Lispro Injection exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much Insulin Lispro Injection to take and when to take it.
• Insulin Lispro Injection starts acting fast. Inject Insulin Lispro Injection within 15 minutes before or right after you eat a meal.
• Know the type, strength and amount 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 taking the correct insulin.

• Inject Insulin Lispro Injection under the skin (subcutaneously) of your stomach area, buttocks, upper legs or upper arms, or 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.

• Change (rotate) your injection sites within the area you choose with 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.
  
  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.

• Always use a new needle for each injection to help prevent infections and blocked needles. Do not reuse or share your needles with other people. You may give other people a serious infection or get a serious infection from them.

• Check your blood sugar levels. Ask your healthcare provider what your blood sugars should be and when you should check your blood sugar levels.

Keep Insulin Lispro Injection and all medicines out of the reach of children.

Your dose of Insulin Lispro Injection may need to change because of a:

• change in 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 Insulin Lispro Injection?

While taking Insulin Lispro Injection do not:

• drive or operate heavy machinery, until you know how Insulin Lispro Injection affects you.

• drink alcohol or take prescription or over-the-counter medicines that contain alcohol.

What are the possible side effects of Insulin Lispro Injection?

Insulin Lispro Injection may cause serious side effects that can lead to death, including:

• low blood sugar (hypoglycemia). Signs and symptoms of low blood sugar may include:
  
  o dizziness or light-headedness
  o sweating
  o confusion
  o headache
  o blurred vision
  o slurred speech
  o Shakiness
  o Fast heartbeat
  o Anxiety, irritability, or mood changes
  o Hunger

Your healthcare provider may prescribe a glucagon emergency kit so that someone else can give you glucagon if your blood sugar becomes too low (severe hypoglycemia) and you are unable to take sugar by mouth.

• serious allergic reactions (whole body allergic reaction). Get medical help right away, if you have any of these signs or symptoms of a severe allergic reaction:
  
  o a rash over your whole body
  o trouble breathing
  o a fast heartbeat
  o sweating
  o feel faint

• low potassium in your blood (hypokalemia).
• heart failure. Taking certain diabetes pills called thiazolidinediones or “TZDs” with Insulin Lispro Injection may cause heart failure in some people. This can happen even if you have never had heart failure or heart
problems before. If you already have heart failure it may get worse while you take TZDs with Insulin Lispro Injection. Your healthcare provider should monitor you closely while you are taking TZDs with Insulin Lispro Injection. 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

Treatment with TZDs and Insulin Lispro Injection may need to be adjusted or stopped by your healthcare provider if you have new or worse heart failure.

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
- confusion

The most common side effects of Insulin Lispro Injection include:

- low blood sugar (hypoglycemia)
- reactions at your injection site
- skin thickening or pits at the injection site (lipodystrophy)
- weight gain
- swelling in your hands or feet
- itching
- rash

These are not all the possible side effects of Insulin Lispro Injection. 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 Insulin Lispro Injection.

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

This Patient Information leaflet summarizes the most important information about Insulin Lispro Injection. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Insulin Lispro Injection that is written for health professionals.

What are the ingredients in Insulin Lispro Injection?

**Active ingredient:** insulin lispro

**Inactive ingredients:** dibasic sodium phosphate, glycerin, metacresol, zinc oxide (zinc ion), trace amounts of phenol and Water for Injection, USP

Manufactured by Eli Lilly and Company Indianapolis, IN 46285, USA

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For more information, call 1-800-545-5979.

This Patient Information has been approved by the U.S. Food and Drug Administration

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