

Patient Information
HUMALOG KwikPen®
insulin lispro injection
U-200 (200 units per mL)

Do not share your HUMALOG KwikPen 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 HUMALOG?

- HUMALOG is a rapid-acting man-made insulin used to control high blood sugar in adults and children with diabetes mellitus.
- This HUMALOG KwikPen (“Pen”) contains **2** times as much insulin (200U/mL) in 1 mL as standard insulin (100U/mL).
- It is not known if HUMALOG is safe and effective in children less than 3 years of age.
- It is not known if HUMALOG is safe and effective in children with type 2 diabetes.

Who should not take HUMALOG?

Do not take HUMALOG if you:

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

What should I tell my healthcare provider before using HUMALOG?

Before using HUMALOG, tell your healthcare provider about all your medical conditions, including if you:

- have liver or kidney problems
- take 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 HUMALOG.
- are pregnant, planning to become pregnant, or breastfeeding. It is not known if HUMALOG may harm your unborn or breastfeeding baby.

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

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

How should I use HUMALOG KwikPen?

- Read the detailed **Instructions for Use** that come with your HUMALOG KwikPen.
- Use HUMALOG KwikPen exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much HUMALOG to use and when to use it.
- Know the amount of HUMALOG you use. **Do not** change the amount of HUMALOG you use unless your healthcare provider tells you to.
- Check your insulin label each time you give your injection to make sure you are using the correct insulin.
- HUMALOG comes in a KwikPen which is a disposable prefilled pen that you must use to give your HUMALOG. The dose window on your pen shows your dose of HUMALOG. **Do not** make any dose changes unless your healthcare provider tells you to.
- **Do not** use a syringe to remove HUMALOG from your KwikPen disposable prefilled pen.
- **Do not** re-use needles. Always use a new needle for each injection. Re-use of needles increases your risk of having blocked needles, which may cause you to get the wrong dose of HUMALOG. Using a new needle for each injection also lowers your risk of getting an infection. If your needle is blocked, follow the instructions in the “**General information about the safe and effective use of your Pen**” section of the Instructions for Use.
- HUMALOG is a rapid-acting insulin. Take HUMALOG **within 15** minutes before eating or right after eating a meal.
- Inject HUMALOG under your skin (subcutaneously). **Do not** use HUMALOG KwikPen (“Pen”) in an insulin pump or inject HUMALOG KwikPen into your vein (intravenously).
- Change (rotate) your injection site with each dose.
- **Do not** mix the HUMALOG in the HUMALOG KwikPen with any other type of insulin or liquid medicine.
- **Check your blood sugar levels.** Ask your healthcare provider what your blood sugar should be and when you should check your blood sugar levels.

Keep HUMALOG KwikPen and all medicines out of reach of children.

Your dose of HUMALOG 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 using HUMALOG KwikPen?

While using HUMALOG KwikPen do not:

- drive or operate heavy machinery, until you know how HUMALOG KwikPen affects you

- drink alcohol or use over-the-counter medicines that contain alcohol

What are the possible side effects of HUMALOG?

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

- **low blood sugar (hypoglycemia).** Signs and symptoms of low blood sugar may include:
 - dizziness or lightheadedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability or mood changes, hunger.
- **severe allergic reaction (whole body reaction).** **Get medical help right away, if you have any of these signs or symptoms of a severe allergic reaction:**
 - a rash over your whole body, have trouble breathing, a fast heartbeat, or sweating.
- **low potassium in your blood (hypokalemia).**
- **heart failure.** Taking certain diabetes pills called TZDs (thiazolidinediones) with HUMALOG 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 HUMALOG. Your healthcare provider should monitor you closely while you are taking TZDs with HUMALOG. 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, sudden weight gain

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

Get emergency 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 HUMALOG include:

- low blood sugar (hypoglycemia), allergic reactions, including reactions at your injection site, skin thickening or pits at the injection site (lipodystrophy), itching, and rash.

These are not all of the possible side effects from HUMALOG. 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 HUMALOG KwikPen.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. **Do not** use HUMALOG for a condition for which it was not prescribed. **Do not** give HUMALOG 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 HUMALOG KwikPen. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about HUMALOG that is written for healthcare providers. For more information go to www.humalog.com or call 1-800-LillyRx (1-800-545-5979).

What are the ingredients in HUMALOG U-200?

Active ingredient: insulin lispro.

Inactive ingredient: glycerin, tromethamine, metacresol, zinc oxide (zinc ion), trace amounts of phenol and water for injection.

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For more information, go to www.humalog.com.

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