

PATIENT INFORMATION
HUMALOG® (HU-ma-log) KwikPen®
(insulin lispro)
injection, for subcutaneous use
200 units per mL

Do not share your HUMALOG KwikPen or needles 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 single-patient-use HUMALOG U-200 KwikPen (“Pen”) contains **2** times as much insulin (200 units per mL) in 1 mL as HUMALOG U-100 KwikPen (100 units per mL).

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 taking HUMALOG?

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

- have liver or kidney 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 HUMALOG.
- are pregnant or plan to become pregnant. Talk to 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 HUMALOG.

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 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 comes 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 take and when to take it.
- 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.
- HUMALOG comes in a KwikPen which is a disposable single-patient-use 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. Inject HUMALOG within 15 minutes before or right after eating a meal.**
- Inject HUMALOG under the skin (subcutaneously) of your stomach area, buttocks, upper legs or upper arms. **Do not** use HUMALOG KwikPen (“Pen”) in an insulin pump or inject HUMALOG KwikPen into your vein (intravenously).
- **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.

- **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 take prescription or 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:
 - 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 product for emergency use 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.

- **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:

- o a rash over your whole body
- o trouble breathing
- o a fast heartbeat
- o sweating

- **low potassium in your blood (hypokalemia).**

- **heart failure.** Taking certain diabetes pills called thiazolidinediones or “TZDs” 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:

- o shortness of breath
- o swelling of your ankles or feet
- o 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 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 HUMALOG 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 of the possible side effects of 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 take 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 professionals.

What are the ingredients in HUMALOG U-200?

Active ingredient: insulin lispro.

Inactive ingredient: glycerin, metacresol, trace amounts of phenol, tromethamine, zinc oxide (zinc ion), and Water for Injection, USP.

Humalog® and Humalog KwikPen® are registered trademarks of Eli Lilly and Company.

Manufactured by: Eli Lilly and Company, Indianapolis, IN 46285, USA, US License Number 1891
Copyright © 2015, 2023, Eli Lilly and Company. All rights reserved.
For more information, go to www.humalog.com or call 1-800-545-5979.

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

Revised: July 2023

LOG200-0004-PPI-20230721