

## Patient Information

### **HUMALOG® (HU-ma-log) (insulin lispro injection, USP [rDNA origin]) for injection**

#### **What is HUMALOG?**

- HUMALOG 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 HUMALOG 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 use HUMALOG?**

##### **Do not use HUMALOG if you:**

- are having an episode of low blood sugar (hypoglycemia).
- have an allergy to HUMALOG or any of the ingredients in HUMALOG.

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

- **have kidney or liver problems.**
- take any other medicines, especially ones commonly 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.
- **have any other medical conditions.** Some medical conditions can affect your insulin needs and your dose of HUMALOG.
- **are pregnant or plan to become pregnant.** Talk to your healthcare provider if you are pregnant or plan to become pregnant. You and your healthcare provider should decide about the best way to manage your diabetes while you are pregnant.
- **are breastfeeding or plan to breastfeed.** It is not known if HUMALOG passes into your breast milk. You and your healthcare provider should decide if you will use HUMALOG while you breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription or over-the-counter medicines, vitamins, or 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?**

- Read the **Instructions for Use** that come with your HUMALOG.
- **Do not share your Humalog KwikPen, cartridges, reusable pen compatible with Lilly 3 mL cartridges, 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.**
- Use HUMALOG exactly as your healthcare provider tells you to.
- **HUMALOG starts acting fast**, so inject it up to 15 minutes before or right after you eat a meal.

- Know the type and strength of insulin you use. **Do not** change the type of insulin you use 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 a different type of 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.

### **What should I avoid while using HUMALOG?**

#### **While using HUMALOG do not:**

- Drive or operate heavy machinery, until you know how HUMALOG affects you.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

### **What are the possible side effects of HUMALOG?**

#### **HUMALOG may cause serious side effects, 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.

#### **Your HUMALOG dose may need to change because of a:**

- change in level of physical activity or exercise, weight gain or loss, change in diet, illness.
- **serious allergic reactions (whole body allergic reaction). Get medical help right away, if you have any of these symptoms of an allergic reaction:**
  - a rash over your whole body, trouble breathing, a fast heartbeat, sweating, feel faint.
- **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:
  - 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.

#### **The most common side effects of HUMALOG include:**

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

These are not all 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.**

- Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about HUMALOG that is written for health professionals.
- Do not use HUMALOG for a condition for which it was not prescribed. **Do not** give or share HUMALOG with other people, even if they also have diabetes. It may harm them.

**What are the ingredients in HUMALOG?**

**Active ingredient:** insulin lispro

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

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**Marketed by: Lilly USA, LLC, Indianapolis, IN 46285, USA**

For more information, go to [www.humalog.com](http://www.humalog.com) or call 1-800-545-5979.

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

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