

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

Do not share your Humalog prefilled pens, cartridges, reusable pen compatible with Lilly 3 mL cartridges, needles, 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 HUMALOG?

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

Who should not take HUMALOG?

Do not take HUMALOG if you:

- are having an episode of low blood sugar (hypoglycemia).
- have an allergy to HUMALOG 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 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 HUMALOG.
- 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 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 take HUMALOG?

- Read the **Instructions for Use** that comes with your HUMALOG.
- Take HUMALOG exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much HUMALOG to take and when to take it.
- **HUMALOG starts acting fast. Inject HUMALOG 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 HUMALOG 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 HUMALOG and all medicines out of the 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 taking HUMALOG?

While taking HUMALOG do not:

- drive or operate heavy machinery, until you know how HUMALOG 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 slurred speech
o sweating	o shakiness
o confusion	o fast heartbeat
o headache	o anxiety, irritability or mood changes
o blurred vision	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.

- **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 sweating
o trouble breathing	o feel faint
o a fast heartbeat	
- **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 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. 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. 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 health professionals.

What are the ingredients in HUMALOG?

Active ingredient: insulin lispro

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

Humalog® is a registered trademark of Eli Lilly and Company.

Manufactured by: Eli Lilly and Company, Indianapolis, IN 46285, USA, US License Number 1891

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