

**PART III: CONSUMER INFORMATION**

**HUMALOG® VIALS**

(insulin lispro injection)

Solution for Injection, 100 units/mL, Lilly Standard

**This leaflet is part III of a three-part "Product Monograph" published when HUMALOG® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about HUMALOG®. Contact your doctor or pharmacist if you have any questions about the drug.**

**ABOUT THIS MEDICATION**

**What the medication is used for:**

Insulin is a hormone produced by the pancreas, a large gland that lies near the stomach. This hormone is necessary for the body's correct use of food, especially sugar. Diabetes occurs when the pancreas does not make enough insulin to meet your body's needs.

To control your diabetes, your doctor has prescribed injections of insulin to keep your blood glucose at a near-normal level.

**What it does:**

Insulin lispro is a recombinant DNA sourced human insulin analogue. HUMALOG consists of zinc-insulin lispro crystals dissolved in a clear fluid. HUMALOG is used to control high blood sugar (glucose) in people with diabetes. HUMALOG takes effect more rapidly and has a shorter duration of activity as compared to regular insulin.

The rapid onset of activity requires HUMALOG to be given within 15 minutes before a meal. When necessary, HUMALOG may be given shortly after a meal instead (within 20 minutes of the start of the meal). The time course of action of any insulin may vary to some extent in different individuals or at different times in the same individual. As with all insulin preparations, the duration of action of HUMALOG is dependent on dose, site of injection, blood supply, temperature, and physical activity.

Proper control is important. Uncontrolled diabetes (hyperglycemia) over a long period of time can result in a number of serious problems such as blindness, kidney failure, poor circulation/heart attacks, strokes and/or nerve damage. These problems can be prevented or reduced by good diabetes management. This will require close and constant cooperation with your diabetes healthcare team including: yourself, your doctor and your diabetes educators (nurses, dietitians, social workers, pharmacists and other healthcare professionals). Thus, you can lead an active, healthy and productive life by eating a balanced daily diet, exercising regularly, and taking your insulin injections as prescribed.

You have been instructed to test your blood and/or your urine regularly for glucose. If your blood tests consistently show above- or below-normal glucose levels or your urine tests

consistently show the presence of glucose, your diabetes is not properly controlled and you must let your doctor know.

**When it should not be used:**

- When your blood sugar is too low (hypoglycemia). After treating your low blood sugar, follow your healthcare provider's instructions on the use of HUMALOG.
- If you are allergic to anything in HUMALOG. A complete list of ingredients in HUMALOG is provided below.

**What the medicinal ingredient is:**

HUMALOG contains 100 units/mL of Human Insulin Analogue.

HUMALOG contains insulin lispro injection.

**What the non-medicinal ingredients are:**

HUMALOG contains glycerol, dibasic sodium phosphate, m-cresol, zinc (as ion) and water for injection. Hydrochloric acid or sodium hydroxide may be added to adjust pH.

**What dosage forms it comes in:**

HUMALOG is a sterile solution containing insulin lispro injection. It is available in:

- Vial, 10 mL
- Vial, 3 mL

HUMALOG is also available in:

- Cartridge, 3 mL
- KwikPen, 3 mL prefilled pen
- Junior KwikPen, 3 mL prefilled pen

Other HUMALOG products include:

- HUMALOG 200 units/mL KwikPen (insulin lispro injection)
- HUMALOG MIX25 (25% insulin lispro injection, 75% insulin lispro protamine suspension)
- HUMALOG MIX50 (50% insulin lispro injection, 50% insulin lispro protamine suspension)

**DO NOT USE ANY OTHER INSULIN EXCEPT ON YOUR DOCTOR'S ADVICE AND DIRECTION.**

Always keep an extra supply of HUMALOG as well as a spare syringe and needle or injection device on hand. Always wear identification to indicate that you have diabetes so that appropriate treatment can be given if complications occur away from home.

When you receive your insulin from the pharmacy, always check to see that:

1. The name HUMALOG appears on the carton and bottle (vial) label.
2. The carton and bottle (vial) label is correct for your type of insulin.
3. The insulin strength is U-100.

- The expiration date on the package will allow you to use the insulin before that date.

## **WARNINGS AND PRECAUTIONS**

### **Serious Warnings and Precautions**

- Hypoglycemia or low blood sugar is the most common adverse effect experienced by insulin users. Blood glucose monitoring is recommended for all patients with diabetes. Uncorrected hypoglycemic or hyperglycemic reactions can cause loss of consciousness, coma or even death. Information on how to recognize these symptoms is provided below.
- This Lilly human insulin analogue differs from other insulins because it has a unique structure, a very quick onset of action and a short duration of activity. HUMALOG should be given within 15 minutes before a meal or when necessary shortly after a meal instead (within 20 minutes of the start of the meal). The short duration of action of HUMALOG means that if you have Type 1 diabetes you also need to use a longer-acting insulin to give the best glucose control (except when using an insulin infusion pump).
- HUMALOG should not be used if it is not water-clear and colourless or if it has formed a deposit of solid particles on the wall of the vial.
- Any change of insulin regimen should be made cautiously and only under medical supervision. Changes in purity, strength, brand (manufacturer), type (regular, NPH, etc), species (beef, pork, beef-pork, human), and/or method of manufacture (recombinant DNA versus animal-source insulin) may result in the need for a change in dosage.
- Mixing of HUMALOG with either animal insulins or insulin preparations produced by other manufacturers is not recommended.
- Patients taking HUMALOG may require a change in dosage from that used with other insulins. If an adjustment is needed, it may occur with the first dose or over a period of several weeks.
- Insulin infusion pump: when used in an insulin infusion pump, HUMALOG should not be diluted or mixed with any other insulin. Carefully read and follow the insulin infusion pump manufacturer's instructions and this insert before using HUMALOG.

### **BEFORE you use HUMALOG talk to your doctor or pharmacist if:**

- You have trouble with your kidneys or liver, your doctor may decide to alter your insulin dose.
- You drink alcohol (including wine and beer): watch for signs of hypoglycemia and never drink alcohol on an empty stomach.
- You exercise more than usual or if you want to change your usual diet. Exercise may lower your body's need for insulin during and for some time after the activity. Exercise may

also speed up the effect of an insulin dose, especially if the exercise involves the area of injection site.

- You are ill. Illness, especially with nausea and vomiting, may cause your insulin requirements to change. Even if you are not eating, you will still require insulin. You and your doctor should establish a sick day plan for you to use in case of illness. When you are sick, test your blood/urine frequently.
- You are travelling across more than 2 time zones. You should consult your doctor concerning adjustments in your insulin schedule.
- You are pregnant. HUMALOG can be used in pregnancy if clinically indicated. Data on a large number of exposed pregnancies do not indicate any adverse effect of HUMALOG on pregnancy or on the health of the foetus/newborn. Good control of diabetes is especially important for you and your unborn baby. Pregnancy may make managing your diabetes more difficult. If you are planning to have a baby, are pregnant, or are nursing a baby, consult your doctor.
- When you use other medicines. Many medicines affect the way glucose works in your body and this may influence your insulin dose. Listed below are the most common medicines, which may affect your insulin treatment. Talk to your doctor or pharmacist if you take, or change any other medicines, even those not prescribed.

## **INTERACTIONS WITH THIS MEDICATION**

Insulin requirements may be increased if you are taking other drugs with hyperglycemic activity, such as oral contraceptives (for example, birth control pills, injections and patches), corticosteroids, or thyroid replacement therapy. Insulin requirements may be decreased in the presence of agents such as oral antidiabetic agents, salicylates (aspirin), sulfa antibiotics, certain antidepressants (monoamine oxidase inhibitors), beta-blockers, alcohol, ACE-inhibitors and angiotensin II receptor blockers. Always discuss any medications you are taking with your doctor.

The use of thiazolidinediones (such as rosiglitazone and pioglitazone), alone or in combination with other antidiabetic agents (including insulin), has been associated with heart failure and swelling of the lower extremities. Please contact your physician immediately if you develop symptoms of shortness of breath, fatigue, exercise intolerance, or swelling of the lower extremities while you are on these agents.

## **PROPER USE OF THIS MEDICATION**

HUMALOG is a sterile solution. HUMALOG should be given by subcutaneous injection, or by continuous subcutaneous insulin infusion pump. The concentration of HUMALOG in 3 mL vials or 10 mL vials is 100 units/mL (U-100).

When used as a meal-time insulin, HUMALOG should be given within 15 minutes before a meal, or when necessary shortly after a meal instead (within 20 minutes of the start of the meal).

HUMALOG is a clear and colourless liquid with a water-like appearance and consistency. Do not use if it appears cloudy, thickened, or slightly coloured or if solid particles are visible. Always check the appearance of your vial of HUMALOG before using, and if you note anything unusual in its appearance or notice your insulin requirements changing markedly, consult your doctor.

### **Injection Procedure**

#### *Correct Syringe:*

Doses of insulin are measured in units. HUMALOG is available in 100 units/mL (U-100). It is important that you understand the markings on your syringe, because the volume of HUMALOG you inject depends on the strength, that is, the number of units/mL. For this reason, you should always use a syringe marked for U-100 insulin preparations. Failure to use the proper syringe can lead to a mistake in dosage, causing serious problems for you, such as a blood glucose level that is too low or too high.

#### *Syringe Use:*

To help avoid contamination and possible infection, follow these instructions exactly.

Disposable plastic syringes and needles should be used only once and then discarded in a closable, puncture-resistant sharps container (like a biohazard container) or as directed by your healthcare professional. **NEEDLES AND SYRINGES MUST NOT BE SHARED**, as this may risk transmission of infectious agents.

Reusable glass syringes and needles must be sterilized before each injection. **Follow the package directions supplied with your syringe.**

#### *Preparing the Dose:*

1. Wash your hands.
2. Inspect the HUMALOG in the vial. It should look clear and colourless. Do not use HUMALOG if it appears cloudy, thickened, or slightly coloured or if solid particles are visible.
3. Flip off the plastic protective cap but do not remove the stopper if using a new vial.
4. Wipe the top of the vial with an alcohol swab.
5. If you are mixing insulins, refer to the instructions for mixing below.
6. Remove the cover from the needle. Draw air into the syringe equal to your HUMALOG dose. Put the needle through the rubber top of the HUMALOG vial and inject the air into the vial.
7. Turn the vial and syringe upside down. Hold the vial and syringe firmly in one hand.
8. Making sure the tip of the needle is in the HUMALOG, withdraw the correct dose into the syringe.

9. Before removing the needle from the vial, check your syringe for air bubbles, which reduce the amount of HUMALOG. If bubbles are present, hold the syringe straight up and tap its side until the bubbles float to the top. Push them out with the plunger and withdraw the correct dose.
10. Remove the needle from the vial and lay the syringe down so that the needle does not touch anything.

### **Mixing HUMALOG With Long-Acting Insulin Formulations**

MIXING HUMALOG WITH EITHER ANIMAL INSULINS OR INSULIN PREPARATIONS PRODUCED BY OTHER MANUFACTURERS IS NOT RECOMMENDED.

1. HUMALOG should be mixed with long-acting insulins (HUMULIN N) only on the advice of your doctor.
2. Draw air into your syringe equal to the amount of longer-acting HUMULIN insulin you are taking. Insert the needle into the long-acting insulin vial and inject the air, taking care not to come in contact with the insulin in the vial. Withdraw the needle.
3. Now inject air into your HUMALOG vial in the same manner, but do not withdraw the needle.
4. Turn the vial and syringe upside down.
5. Making sure the tip of the needle is in the HUMALOG, withdraw the correct dose of HUMALOG into the syringe.
6. Before removing the needle from the vial of HUMALOG, check your syringe for air bubbles, which reduce the amount of HUMALOG in it. If bubbles are present, hold the syringe straight up and tap its side until the bubbles float to the top. Push them out with the plunger and withdraw the correct dose. Gently roll or shake the long-acting HUMULIN vial until the insulin is mixed.
7. Remove the needle from the vial of HUMALOG and insert it into the vial of the long-acting HUMULIN insulin. Turn the vial and syringe upside down. Making sure the tip of the needle is in the insulin, withdraw your dose of long-acting HUMULIN insulin.
8. Remove the needle and lay the syringe down so that the needle does not touch anything.

Follow your doctor's instructions on mixing your insulin just before giving your injection. HUMALOG should be injected immediately after mixing. It is important to be consistent in your method.

Syringes from different manufacturers may vary in the amount of space between the bottom line and the needle. Because of this, do not change the sequence of mixing, or the model and brand of syringe or needle that the doctor has prescribed.

#### *Injection:*

Prepare the injection site as directed by your healthcare professional. To avoid tissue damage (skin thinning, skin thickening, or skin lumps), always change the site for each

injection by at least 1.5 cm (0.5 inches) from the previous site, rotating sites on the body so that the same site is not used more than approximately once a month. Do not inject into pits (depressions), thickened skin or lumps.

Insert the needle as instructed by your doctor. Push the plunger in as far as it will go. Pull the needle out and apply gentle pressure over the injection site for several seconds. Do not rub the area.

### **Use of HUMALOG in an Insulin Infusion Pump:**

1. Health Canada approved insulin infusion pumps may be used to infuse HUMALOG U-100. Read and follow the instructions that accompany the infusion pump.
2. Be sure to use the correct reservoir and catheter for the pump.
3. Change the HUMALOG in the reservoir at least every 14 days. Change the infusion set as recommended in pump manufacturers' instructions (typically every 3 days is recommended) or as directed by your healthcare professional. Use aseptic technique when inserting the infusion set.
4. In the event of a hypoglycemic episode, the infusion should be stopped until the episode is resolved. If repeated or severe low blood glucose levels occur, notify your health care professional and consider the need to reduce or temporarily stop your insulin infusion.
5. A pump malfunction or obstruction of the infusion set can result in a rapid rise in glucose levels. If an interruption to insulin flow is suspected, follow the instructions in the product literature and if appropriate, notify your health care professional.
6. When used with an insulin infusion pump, HUMALOG should not be mixed with any other insulin.

### **Usual dose**

Your doctor has told you which insulin to use, how much, and when and how often to inject it. Because each patient's case of diabetes is different, this schedule has been individualized for you.

Your usual HUMALOG dose may be affected by changes in your food, activity, or work schedule. Carefully follow your doctor's instructions to allow for these changes. Other things that may affect your HUMALOG dose are illness, pregnancy, medication, exercise and travel.

### **Overdose**

Hypoglycemia (too little glucose in the blood) is one of the most frequent adverse events experienced by insulin users. It can be brought about by:

1. Missing or delaying meals
2. Taking too much insulin
3. Exercising or working more than usual
4. An infection or illness (especially with diarrhea or vomiting)
5. A change in the body's need for insulin

6. Diseases of the adrenal, pituitary, or thyroid gland, or progression of kidney or liver disease
7. Interactions with other drugs that lower blood glucose, such as oral hypoglycemics, salicylates, sulfa antibiotics, and certain antidepressants
8. Consumption of alcoholic beverages

### **Dietary Implications:**

If a usual meal cannot be obtained at the appropriate time, then to avoid hypoglycemia, you should take the amount of carbohydrate prescribed for this meal in the form of orange juice, syrup, candy, or bread and milk, without changing your insulin dosage. If it becomes necessary to omit a meal on account of nausea and vomiting, you should test your blood sugar level and notify your doctor.

Mild to moderate hypoglycemia may be treated by eating foods or drinks that contain sugar. Patients should always carry a quick source of sugar, such as candy mints or glucose tablets. More severe hypoglycemia may require the assistance of another person. Patients who are unable to take sugar orally or who are unconscious should be treated with intravenous administration of glucose at a medical facility or should be given an injection of glucagon (either intramuscular or subcutaneous). The patient should be given oral carbohydrates as soon as consciousness is recovered.

In case of drug overdose, contact a healthcare practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

## **SIDE EFFECTS AND WHAT TO DO ABOUT THEM**

### **Hypoglycemia:**

One of the most frequent adverse events experienced by insulin users is hypoglycemia (see PROPER USE OF THIS MEDICATION).

### **Diabetic Acidosis and Coma:**

Diabetic acidosis may develop if your body has too little insulin (this is the opposite of insulin reaction, which is the result of too much insulin in the blood). Diabetic acidosis may be brought on if you omit your insulin or take less than the doctor has prescribed, eat significantly more than your diet calls for, or develop a fever or infection. With acidosis, urine tests show a large amount of sugar and acetone.

The first symptoms of diabetic acidosis usually come on gradually, over a period of hours or days, and include a drowsy feeling, flushed face, thirst, and loss of appetite. Heavy breathing and a rapid pulse are more severe symptoms.

If uncorrected, loss of consciousness, coma, or death can result. Therefore, it is important that you obtain medical assistance immediately.

Lipoatrophy, Lipohypertrophy, or Localized Cutaneous Amyloidosis:

Rarely, administration of insulin subcutaneously can result in lipoatrophy (depression in the skin), lipohypertrophy (enlargement or thickening of tissue), or localized cutaneous amyloidosis (skin lumps). If you notice any of these conditions, consult your doctor. A change in your injection technique may help alleviate the problem.

Allergy to Insulin:

Patients occasionally experience redness, swelling, and itching at the site of injection of insulin. This condition, called local allergy, usually clears up in a few days to a few weeks. If you have local reactions, contact your doctor, who may recommend a change in the type or species of insulin.

Less common, but potentially more serious, is generalized allergy to insulin, which may cause rash over the whole body, shortness of breath, wheezing, reduction in blood pressure, fast pulse, or sweating. Severe cases of generalized allergy may be life threatening. If you think you are having a generalized allergic reaction to insulin, notify a doctor immediately. Your doctor may recommend skin testing, that is, injecting small doses of other insulins into the skin, in order to select the best insulin for you to use. Patients who have had severe generalized allergic reactions to insulin should be skin tested with each new preparation to be used before treatment with that preparation is started.

***This is not a complete list of side effects. For any unexpected effects while taking HUMALOG, contact your doctor or pharmacist.***

**HOW TO STORE IT**

Prior to first use, HUMALOG insulin vials should be stored in a refrigerator between 2° and 8°C. Do not freeze. Do not expose to excessive heat or sunlight. The vial of HUMALOG that you are currently using can be kept unrefrigerated, for up to 28 days, as long as it is kept as cool as possible (below 30°C) and away from direct heat and light. Vials in use, or not refrigerated, should be discarded after 28 days even if they still contain HUMALOG. Do not use HUMALOG if it has been frozen.

**DO NOT USE A VIAL OF HUMALOG AFTER THE EXPIRATION DATE STAMPED ON THE LABEL.**

**REPORTING SUSPECTED SIDE EFFECTS**

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
  - Fax toll-free to 1-866-678-6789, or
  - Mail to:
    - Canada Vigilance Program
    - Health Canada
    - Postal Locator 0701D
    - Ottawa, Ontario
    - K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at [www.healthcanada.gc.ca/medeffect](http://www.healthcanada.gc.ca/medeffect)

*NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.*

**MORE INFORMATION**

For more information, please contact your healthcare professionals or pharmacist first, or Eli Lilly Canada Inc. at: 1-888-545-5972 or visit the website at [www.lilly.ca](http://www.lilly.ca).

The information in this document is current as of the last revision date shown below. For the most current information please visit our website or contact us directly.

This leaflet was prepared by Eli Lilly Canada Inc.

HUMALOG, MIX25, MIX50 and KwikPen are registered trademarks owned by Eli Lilly and Company, its subsidiaries or affiliates.

You may need to read this package insert again. Please do not throw it away until you have finished your medicine.

Last revised: April 12, 2021

LOGVL-0003-CA-PMI-20210412