

INFORMATION FOR THE PATIENT
VIAL

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HUMALOG[®]
INSULIN LISPRO INJECTION
(rDNA ORIGIN)
100 UNITS PER ML (U-100)

WARNINGS

THIS LILLY HUMAN INSULIN ANALOG IS DIFFERENT FROM OTHER INSULINS BECAUSE IT HAS A RAPID ONSET AND SHORTER DURATION OF ACTION. THE RAPID ONSET OF ACTION MEANS THAT YOU SHOULD TAKE YOUR DOSE OF HUMALOG[®] (INSULIN LISPRO INJECTION, rDNA ORIGIN) WITHIN 15 MINUTES BEFORE OR IMMEDIATELY AFTER EATING. 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 EXTERNAL INSULIN PUMP). IF YOU HAVE TYPE 2 DIABETES, HUMALOG MAY BE USED WITHOUT A LONGER-ACTING INSULIN WHEN USED IN COMBINATION THERAPY WITH SULFONYLUREA AGENTS.

ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUSLY AND ONLY UNDER MEDICAL SUPERVISION. CHANGES IN STRENGTH, MANUFACTURER, TYPE (E.G., REGULAR, NPH, LENTE), SPECIES (BEEF, PORK, BEEF-PORK, HUMAN), OR METHOD OF MANUFACTURE (rDNA VERSUS ANIMAL-SOURCE INSULIN) MAY RESULT IN THE NEED FOR A CHANGE IN THE TIMING OR DOSAGE OF HUMALOG OR THE LONGER-ACTING INSULIN, OR BOTH.

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 DURING THE FIRST SEVERAL WEEKS OR MONTHS.

EXTERNAL INSULIN PUMP: WHEN USED IN AN EXTERNAL INSULIN PUMP, HUMALOG SHOULD NOT BE DILUTED OR MIXED WITH ANY OTHER INSULIN. CAREFULLY READ AND FOLLOW THE EXTERNAL INSULIN PUMP MANUFACTURER'S INSTRUCTIONS AND THIS INSERT BEFORE USING HUMALOG (*see* INSTRUCTIONS FOR INSULIN VIAL USE section).

DIABETES

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 products to keep your blood glucose at a near-normal level. You have been instructed to test your blood and/or your urine regularly for glucose. Studies have shown that some chronic complications of diabetes such as eye disease, kidney disease, and nerve disease can be significantly reduced if the blood sugar is maintained as close to normal as possible. The American Diabetes Association recommends that if your pre-meal glucose levels are consistently above 130 mg/dL or your hemoglobin A_{1c}

(HbA_{1c}) is more than 7%, consult your doctor. A change in your diabetes therapy may be needed. If your blood tests consistently show below-normal glucose levels, you should also let your doctor know. Proper control of your diabetes requires close and constant cooperation with your doctor. Despite diabetes, you can lead an active and healthy life if you eat a balanced diet, exercise regularly, and take your insulin injections as prescribed.

Always keep an extra supply of Humalog as well as a spare syringe and needle on hand. Always wear diabetic identification so that appropriate treatment can be given if complications occur away from home.

HUMALOG

Description

Humalog (insulin lispro [rDNA origin]) is made by a special non-disease-producing laboratory strain of *Escherichia coli* bacteria that has been genetically altered by the addition of the gene for this human insulin analog. Humalog consists of zinc-insulin lispro crystals dissolved in a clear fluid. Humalog is a sterile solution and is for subcutaneous injection. It should not be used intramuscularly. The concentration of Humalog is 100 units/mL (U-100). Humalog starts lowering blood glucose more quickly and has a shorter duration of action compared to regular human insulin. This means that your dose of Humalog should be given within 15 minutes before or immediately after a meal (regular insulin works best when given 30 to 60 minutes before a meal). The short duration of action of Humalog means that if you have type 1 diabetes, you need to use a longer-acting insulin to give the best glucose control (except when using an external insulin pump). If you have type 2 diabetes, Humalog may be used without a longer-acting insulin when used in combination therapy with sulfonylurea agents. The time course of Humalog action, like that of other insulins, may vary in different individuals or at different times in the same individual, based on dose, site of injection, blood supply, temperature, and physical activity.

Identification

Insulin lispro injection (rDNA origin), by Eli Lilly and Company, has the trademark Humalog. Your doctor has prescribed the type of insulin that he/she believes is best for you.

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

Always check the carton and bottle labels of the Humalog you receive from your pharmacy to make sure it is the same as that your doctor has prescribed.

Always examine the appearance of Humalog solution in your bottle before withdrawing each dose. Humalog is a clear and colorless liquid with a water-like appearance and consistency. Do not use if it appears cloudy, thickened, or slightly colored, or if solid particles are visible. Always check the appearance of Humalog solution in the bottle before use and if you note anything unusual in its appearance or notice your insulin requirements changing markedly, consult your doctor.

Storage

Humalog may be diluted with the appropriate sterile diluent only under the direction of a physician. **However, do not dilute Humalog when used in an external insulin pump.**

After withdrawal of the initial dose, diluted Humalog should be discarded 28 days after first use when refrigerated and 14 days after first use when stored at room temperature.

Not in-use (unopened): Unopened Humalog bottles should be stored in a refrigerator but not in the freezer. Do not use Humalog if it has been frozen.

In-use: Humalog bottles should be refrigerated after first dose has been withdrawn. If refrigeration is not possible, the bottle of Humalog that you are currently using can be kept unrefrigerated, up to 28 days, as long as it is kept at room temperature (below 86°F [30°C]) and away from direct heat and light. Do not use Humalog if it has been frozen.

Humalog in the external insulin pump reservoir and the complete infusion set should be replaced and a new infusion site selected every 48 hours or less. Humalog in an external insulin

pump should not be exposed to temperatures above 98.6°F (37°C), such as in a sauna or hot tub, hot showers, direct sunlight, or radiant heater.

Do not use Humalog after the expiration date stamped on the label or if it has been frozen.

INSTRUCTIONS FOR INSULIN VIAL USE

Use with Syringes

NEVER SHARE NEEDLES AND SYRINGES.

Correct Syringe Type

Doses of insulin are measured in **units**. U-100 insulin contains 100 units/mL (1 mL = 1 cc). With Humalog, it is important to use a syringe that is marked for U-100 insulin preparations. For this reason, you should always use a syringe marked for the strength of Humalog you are injecting. 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 responsible manner. Place the used needle in a puncture-resistant disposable container and properly dispose of it as directed by your Health Care Professional.

Reusable glass syringes and needles must be sterilized before each injection. **Follow the package directions supplied with your syringe.** Described below are 2 methods of sterilizing.

Boiling

1. Put syringe, plunger, and needle in strainer, place in saucepan, and cover with water. Boil for 5 minutes.
2. Remove articles from water. When they have cooled, insert plunger into barrel, and fasten needle to syringe with a slight twist.
3. Push plunger in and out several times until water is completely removed.

Isopropyl Alcohol

If the syringe, plunger, and needle cannot be boiled, as when you are traveling, they may be sterilized by immersion for at least 5 minutes in Isopropyl Alcohol, 91%. Do not use bathing, rubbing, or medicated alcohol for this sterilization. If the syringe is sterilized with alcohol, it must be absolutely dry before use.

Preparing the Dose

1. Wash your hands.
2. Inspect the appearance of Humalog solution in the bottle. It should look clear and colorless. Do not use Humalog if it appears cloudy, thickened, or slightly colored, or if solid particles are visible.
3. If using a new bottle, flip off the plastic protective cap, but **do not** remove the stopper.
4. Wipe the top of the bottle with an alcohol swab.
5. If you are mixing insulins, refer to the instructions for mixing that follow.
6. Draw air into the syringe equal to your Humalog dose. Put the needle through rubber top of the Humalog bottle and inject the air into the bottle.
7. Turn the bottle and syringe upside down. Hold the bottle 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 bottle, 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 bottle and lay the syringe down so that the needle does not touch anything.

Mixing Humalog with Longer-acting Human Insulins

Humalog should not be mixed with any other insulin when used in an external insulin pump.

1. Humalog should be mixed with longer-acting human insulins only on the advice of your doctor.
2. Draw air into your syringe equal to the amount of longer-acting insulin you are taking. Insert the needle into the longer-acting insulin bottle and inject the air. Withdraw the needle.
3. Now inject air into your Humalog bottle in the same manner, but **do not** withdraw the needle.
4. Turn the bottle and syringe upside down.
5. Making sure the tip of the needle is in the Humalog solution, withdraw the correct dose of Humalog into the syringe.
6. Before removing the needle from the bottle 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.
7. Remove the needle from the bottle of Humalog and insert it into the bottle of the longer-acting insulin. Turn the bottle and syringe upside down. Hold the bottle and syringe firmly in one hand and shake gently. Making sure the tip of the needle is in the insulin, withdraw your dose of longer-acting insulin.
8. Remove the needle and lay the syringe down so that the needle does not touch anything.

When you are mixing two types of insulin, always draw Humalog into the syringe first. Always mix the insulin preparations in this same sequence in order to maintain purity of the Humalog vial. You should inject your insulins immediately after mixing.

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

Once you have chosen an injection site, cleanse the skin with alcohol where the injection is to be made. Stabilize the skin by spreading it or pinching up a large area. 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.** To avoid tissue damage, give the next injection at a site at least 1/2 inch from the previous injection site. The usual sites of injection are abdomen, thighs, and arms. Place the used needle in a puncture-resistant disposable container and properly dispose of it as directed by your Health Care Professional.

Use in an External Insulin Pump

Your doctor should train you on intensive insulin therapy. You should also be trained on the use of your external insulin pump and pump accessories.

Humalog may be used with the MiniMed®¹ Models 506, 507, and 508 insulin pumps using MiniMed®¹ Polyfin®¹ infusion sets. Humalog may also be used in the Disetronic®² H-TRONplus® V100 insulin pump (with plastic 3.15 mL insulin reservoir), using the Disetronic®² Rapid®² infusion set.

Follow the external insulin pump manufacturer's instructions for use of Humalog in an external insulin pump. Humalog should not be diluted or mixed with any other insulin when used in an external insulin pump.

You should replace the infusion set (reservoir syringe, tubing, and catheter) and Humalog in the external insulin pump reservoir every 48 hours or less. You should also choose a new

infusion site every 48 hours or less. Contact your doctor if your infusion sites are red, itching, or thickened, and then choose a new infusion site.

DOSAGE

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

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 glucose/urine glucose and ketones frequently and call your doctor as instructed.

Pregnancy

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. Humalog has not been tested in pregnant or nursing women.

Geriatric Use

Elderly patients using Humalog had HbA_{1c} values and hypoglycemia rates similar to those observed in younger patients. The onset of action of Humalog may be different in elderly patients.

Medication

Insulin requirements may be increased if you are taking other drugs with hyperglycemic activity, such as oral contraceptives, corticosteroids, or thyroid replacement therapy. Insulin requirements may be reduced in the presence of drugs with blood-glucose-lowering activity, such as oral antidiabetic agents, salicylates (for example, aspirin), sulfa antibiotics, alcohol, and certain antidepressants. Your Health Care Professional is aware of other medications that may affect your diabetes control. Therefore, always discuss any medications you are taking with your doctor.

Exercise

Exercise may lower your body's need for insulin products during and for some time after the physical activity. Exercise may also speed up the effect of a dose of Humalog, especially if the exercise involves the area of injection site. Discuss with your doctor how you should adjust your regimen to accommodate exercise.

Travel

Persons traveling across more than 2 time zones should consult their doctor concerning adjustments in their insulin schedule.

COMMON PROBLEMS OF DIABETES

Hypoglycemia (Low Blood Sugar)

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 antidiabetic agents, salicylates (for example, aspirin), sulfa antibiotics, and certain antidepressants.
8. Consumption of alcoholic beverages.

Symptoms of mild to moderate hypoglycemia may occur suddenly and can include:

- sweating
- dizziness
- palpitation
- tremor
- hunger
- restlessness
- tingling in the hands, feet, lips, or tongue
- lightheadedness
- inability to concentrate
- headache
- drowsiness
- sleep disturbances
- anxiety
- blurred vision
- slurred speech
- depressed mood
- irritability
- abnormal behavior
- unsteady movement
- personality changes

Signs of severe hypoglycemia can include:

- disorientation
- unconsciousness
- seizures
- death

Therefore, it is important that assistance be obtained immediately.

Early warning symptoms of hypoglycemia may be different or less pronounced under certain conditions, such as long duration of diabetes, diabetic nerve disease, use of medications such as beta-blockers, changing insulin preparations, or intensified control (3 or more injections per day) of diabetes. A few patients who have experienced hypoglycemic reactions after transfer from animal-source insulin to human insulin have reported that the early warning symptoms of hypoglycemia were less pronounced or different from those experienced with their previous insulin.

Without recognition of early warning symptoms, you may not be able to take steps to avoid more serious hypoglycemia. Be alert for all of the various types of symptoms that may indicate hypoglycemia. Patients who experience hypoglycemia without early warning symptoms should monitor their blood glucose frequently, especially prior to activities such as driving. If the blood glucose is below your normal fasting glucose, you should consider eating or drinking sugar-containing foods to treat your hypoglycemia.

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 require an injection of glucagon or should be treated with intravenous administration of glucose at a medical facility.

You should learn to recognize your own symptoms of hypoglycemia. If you are uncertain about these symptoms, you should monitor your blood glucose frequently to help you learn to recognize the symptoms that you experience with hypoglycemia.

If you have frequent episodes of hypoglycemia or experience difficulty in recognizing the symptoms, you should consult your doctor to discuss possible changes in therapy, meal plans, and/or exercise programs to help you avoid hypoglycemia.

Hyperglycemia and Diabetic Ketoacidosis (DKA)

Hyperglycemia (too much glucose in the blood) may develop if your body has too little insulin. Hyperglycemia can be brought about by any of the following:

1. Omitting your insulin or taking less than the doctor has prescribed.
2. Eating significantly more than your meal plan suggests.
3. Developing a fever, infection, or other significant stressful situation.

In patients with type 1 or insulin-dependent diabetes, prolonged hyperglycemia can result in DKA. The first symptoms of DKA usually come on gradually, over a period of hours or days, and include a drowsy feeling, flushed face, thirst, loss of appetite, and fruity odor on the breath.

With DKA, urine tests show large amounts of glucose and ketones. Heavy breathing and a rapid pulse are more severe symptoms. If uncorrected, prolonged hyperglycemia or DKA can lead to nausea, vomiting, dehydration, loss of consciousness, or death. Therefore, it is important that you obtain medical assistance immediately.

Lipodystrophy

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

Allergy

Local Allergy — Patients occasionally experience redness, swelling, and itching at the site of injection. This condition, called local allergy, usually clears up in a few days to a few weeks. In some instances, this condition may be related to factors other than insulin, such as irritants in the skin cleansing agent or poor injection technique. If you have local reactions, contact your doctor.

Systemic Allergy — 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, notify a doctor immediately.

ADDITIONAL INFORMATION

Additional information about diabetes may be obtained from your diabetes educator.

DIABETES FORECAST is a magazine designed especially for people with diabetes and their families. It is available by subscription from the American Diabetes Association (ADA), P.O. Box 363, Mt. Morris, IL 61054-0363, 1-800-DIABETES (1-800-342-2383).

Another publication, **COUNTDOWN**, is available from the Juvenile Diabetes Research Foundation International (JDRFI), 120 Wall Street 19th Floor, New York, NY 10005, 1-800-533-CURE (1-800-533-2873).

Additional information about Humalog can be obtained by calling The Lilly Answers Center at 1-800-LillyRx (1-800-545-5979).

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² Disetronic®, H-TRONplus®, and Rapid® are registered trademarks of Roche Diagnostics GMBH. Other product and company names may be the trademarks of their respective owners.

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