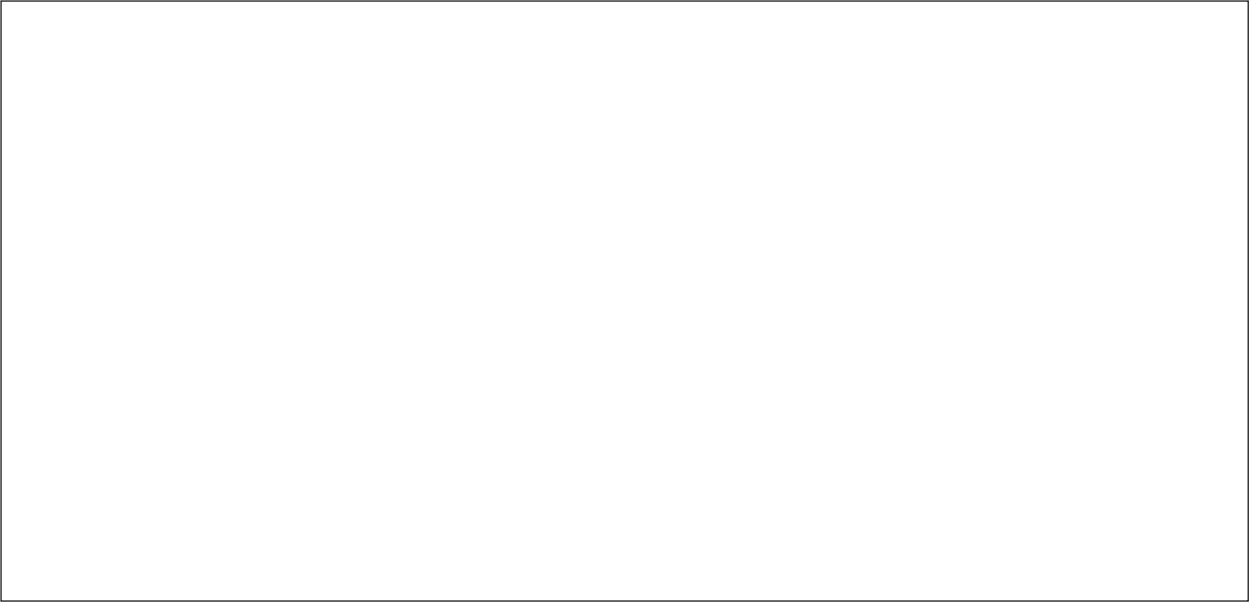


Managing
Your
Diabetes[®]

Self-Care Diary



Lilly



Name _____

Address _____

City _____

State _____ Zip _____

Telephone _____

I have diabetes.

In case of emergency, please call:

Name _____

Address _____

Telephone _____

Doctor's Name _____

Telephone _____

Hospital _____

Pharmacy _____

Telephone _____

Diabetes Educator's Name _____

Telephone _____

Staying in Control

One of the best things you can do to stay in control of your diabetes is to maintain your **blood sugar** levels and **A1C** results within the target range set by you, your doctor and/or your diabetes educator. To know whether your blood sugar levels are in range, you need to check your blood sugar throughout the day and have an A1C test performed at your doctor's office at least every three to six months. (Talk to your doctor or diabetes educator for more information about how to check your A1C.)

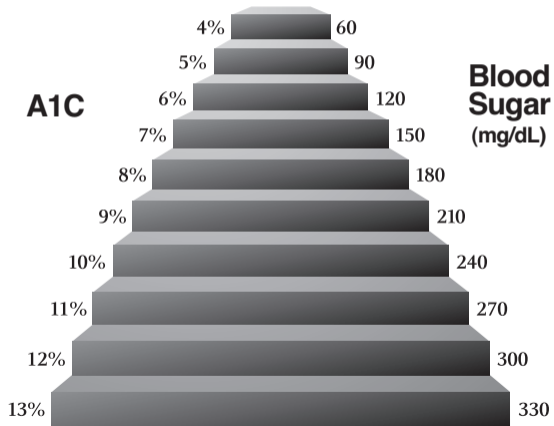
Both tests provide you and your healthcare team with important information about your blood sugar control. Your home blood sugar result is like a snap shot. It tells you what your blood sugar level is at the exact time you check it. The A1C result tells you what your average blood sugar has been for the past two months. When you meet with your doctor or diabetes educator to set your goals for these tests,

complete the section of this diary called “Your Diabetes Plan” so you will always know your target ranges.

Keep your diary up-to-date and take it when you visit your healthcare team. This will help them find any patterns (such as high blood sugar levels in the morning) that may require changes to your medication or meal plan to improve control. By making regular, daily entries in this diary, you will be an active partner in maintaining the best possible control over your diabetes.

How to Compare Values

This chart shows the average blood sugar that corresponds to the A1C test results.* Your doctor and/or diabetes educator will help you set your goal.



* Reference: Diabetes Control and Complications Trial (DCCT): Results of Feasibility Trial. Diabetes Care. Volume 10: 1-19, 1987.

Meal Planning

Despite what you may have heard, having diabetes does not mean you have to give up the foods you enjoy. However, learning to eat healthy, satisfying meals is an important part of your treatment. Starches and sugars (*carbohydrates*) have more effect on blood sugar than protein or fat. By keeping track of the carbohydrates you eat and spreading them throughout the day, you can help control your blood sugar. Your healthcare team can help you learn what is right for you and can list the amounts in the chart below.

	Breakfast	Lunch	Dinner	Snack
Carbohydrates				
Other				

Health Checklist

Here are some key things you need to do to stay feeling your best. Be sure to list your test values and information in the chart below for your own records. Keep this handy and refer to it often. **When you start a new diary, write down your last test result in the new diary.**

My Health Record	Date _____	Date _____	Date _____	Date _____
Every Visit:				
Blood Pressure				
Weight				
Visual Foot Exam				
Every 3–6 Months:				
A1C				
A1C Normal Range				
Every Year:				

Total Cholesterol				
HDL Cholesterol				
LDL Cholesterol				
Triglycerides				
Kidney Checks				
Comprehensive Foot Exam				
Dilated Eye Exam				

- See your doctor and/or diabetes educator at least every 3–6 months
- Work with your health care team to set your personal goals
- Blood pressure check at every visit
- Visual foot exam every visit; comprehensive foot exam at least every year
- Have an A1C test at least every 3–6 months
- Check blood fats (lipids) at least every year
- Kidney check (microalbumin) at least every year
- Dilated eye exam at least every year*

* Yearly exams for all people with type 2 diabetes. Yearly exams for people with type 1 diabetes beginning 5 years after diagnosis.

Your Diabetes Plan

Fill out this page when you meet with your doctor or diabetes educator so you know your target ranges, the dose and type of diabetes medicine you should be taking, as well as your blood sugar testing schedule.

Diabetes Medicine

Time	Type	Dose/Units

Blood Sugar Target Ranges

Before Meals _____ mg/dL to _____ mg/dL

2 Hours

After Meals _____ mg/dL to _____ mg/dL

A1C Target Goal

Less than: _____ %

3 Write in the units and type of insulin on the line that shows the time it was taken.

4 Write in any other diabetes medications that you and your doctor may want to track and the time you take each dose.

5 Write in any special notes you think may be important to know (such as a big meal, illness, stress, exercise, urine ketone test result, etc.).

Insulin	Morning	Noon	Evening	Bedtime	Oral Agent(s)	Comments (illness, reactions, urine ketones, activities)
Monday Units / Type	3				4	5
Tuesday Units / Type	4H 7N	5H	9H	14N		EXERCISED AFTER DINNER AND HAD LOW SUGAR
Wednesday Units / Type	↓	↓	↓	↓		
Thursday Units / Type						NOT FEELING WELL, KETONES NEG
Friday Units / Type						
Saturday Units / Type						
Sunday Units / Type						

Insulin	Morning	Noon	Evening	Bedtime	Oral Agent(s)	Comments (illness, reactions, urine ketones, activities)
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Sunday Units / Type						

INFORMATION FOR THE PATIENT
3 ML DISPOSABLE INSULIN DELIVERY DEVICE
HUMALOG® Pen
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. 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.

TO OBTAIN AN ACCURATE DOSE, CAREFULLY READ AND FOLLOW THE “DISPOSABLE INSULIN DELIVERY DEVICE USER MANUAL” AND THIS INFORMATION FOR THE PATIENT INSERT BEFORE USING THIS PRODUCT. BEFORE EACH INJECTION, YOU SHOULD PRIME THE PEN, A NECESSARY STEP TO MAKE SURE THE PEN IS READY TO DOSE. PRIMING THE PEN IS IMPORTANT TO CONFIRM THAT INSULIN COMES OUT WHEN YOU PUSH THE INJECTION BUTTON AND TO REMOVE AIR THAT MAY COLLECT IN THE INSULIN CARTRIDGE DURING NORMAL USE. IF YOU DO NOT PRIME, YOU MAY RECEIVE TOO MUCH OR TOO LITTLE INSULIN (*see also* INSTRUCTIONS FOR PEN 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 premeal 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 30-60 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. If you have type 2 diabetes, Humalog may be used without a longer-acting insulin when used in combination therapy with sulfonyleurea 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), manufactured 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.

The Humalog Pen is available in boxes of 5 disposable insulin delivery devices ("insulin Pens"). The Humalog Pen is not designed to allow any other insulin to be mixed in its cartridge of Humalog, or for the cartridge to be removed.

HUMALOG® Pen INSULIN LISPRO INJECTION (rDNA ORIGIN)

PV 3700 AMP

Always examine the appearance of Humalog solution in the insulin Pen before administering a 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. If you note anything unusual in its appearance or notice your insulin requirements changing markedly, consult your doctor.

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

In-use: Humalog Pens in-use should **NOT** be refrigerated but should be kept at room temperature (below 86°F [30°C]) away from direct heat and light. Humalog Pens in-use must be discarded **after 28 days**, even if they still contain Humalog.

Do not use Humalog Pens after the expiration date stamped on the label.

INSTRUCTIONS FOR PEN USE:

It is important to read, understand, and follow the instructions in the "Disposable Insulin Delivery Device User Manual" before using. Failure to follow instructions may result in getting too much or too little insulin. The needle must be changed and the Pen must be primed before each injection to make sure the Pen is ready to dose. These steps are important to confirm that insulin comes out when you push the injection button, and to remove air that may collect in the insulin cartridge during normal use.

Every time you inject:

- Use a new needle
- Prime to make sure the pen is ready to dose
- Make sure you got a full dose

NEVER SHARE INSULIN PENS, CARTRIDGES, OR NEEDLES.

PREPARING THE INSULIN PEN FOR INJECTION

1. Inspect the appearance of Humalog solution in the Humalog Pen. It should look clear and colorless. Do not use Humalog if it appears cloudy, thickened, or slightly colored, or if solid particles are visible.

HUMALOG® Pen INSULIN LISPRO INJECTION (rDNA ORIGIN)

PV 3700 AMP

2. Follow the instructions in the “Disposable Insulin Delivery Device User Manual” for these steps:

- Preparing the Pen
- Attaching the Needle. **Use a new needle for each injection.**
- Priming the Pen. **The Pen must be primed before each injection to make sure the Pen is ready to dose.** Performing the priming step is important to confirm that insulin comes out when you push the injection button, and to remove air that may collect in the insulin cartridge during normal use.
- Setting a Dose
- Injecting a Dose. **To make sure you have received your dose, you must push the injection button all the way down until you see a diamond (◆) or an arrow (→) in the center of the dose window.**
- Following an Injection

PREPARING FOR INJECTION

1. Wash your hands.
2. To avoid tissue damage, choose a site for each injection that is at least 1/2 inch from the previous injection site. The usual sites of injection are abdomen, thighs, and arms.
3. Cleanse the skin with alcohol where the injection is to be made.
4. With one hand, stabilize the skin by spreading it or pinching up a large area.
5. Inject the dose as instructed by your doctor.
6. After dispensing a dose, pull the needle out and apply gentle pressure over the injection site for several seconds. Do not rub the area.
7. Immediately after an injection, remove the needle from the Humalog Pen. Doing so will guard against contamination, and prevent leakage of Humalog, reentry of air, and

needle clogs. **Do not reuse needles.** Place the used needle in a puncture-resistant disposable container and properly dispose of it as directed by your Health Care Professional.

DOSAGE: Your doctor has told you which insulin to use, how much, and when and how often to inject it. Because each patient’s diabetes is different, this schedule has been individualized for you. Your usual dose of Humalog 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 dose of Humalog 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 hypoglycemics, 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 (Insulin Reaction)—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 (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
- drowsiness
- sleep disturbances
- anxiety
- blurred vision
- slurred speech
- depressed mood

- tingling in the hands, feet, lips, or tongue
- lightheadedness
- inability to concentrate
- headache
- 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 Acidosis—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 insulin-dependent diabetes, prolonged hyperglycemia can result in diabetic acidosis. 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, loss of appetite, and fruity odor on the breath. With acidosis, urine tests show large amounts of glucose and acetone. Heavy breathing and a rapid pulse are more severe symptoms. If uncorrected, prolonged hyperglycemia or diabetic acidosis 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 national magazine designed especially for patients with diabetes and their families and is available by subscription from the American Diabetes Association, National Service Center, 1660 Duke Street, Alexandria, Virginia 22314, 1-800-DIABETES (1-800-342-2383). Another publication, **DIABETES COUNTDOWN**, is available from the Juvenile Diabetes Foundation International (JDF), 120 Wall Street, 19th Floor, New York, New York 10005-4001, 1-800-JDF-CURE (1-800-533-2873).

Additional information about Humalog and Humalog Pen can be obtained by calling 1-888-88-LILLY (1-888-885-4559).

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PV 3700 AMP

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Indianapolis, IN 46285, USA

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INFORMATION FOR THE PATIENT
3 ML DISPOSABLE INSULIN DELIVERY DEVICE
HUMALOG® Mix75/25™ Pen
75% INSULIN LISPRO PROTAMINE SUSPENSION
AND 25% INSULIN LISPRO INJECTION
(rDNA ORIGIN)
100 UNITS PER ML (U-100)

WARNINGS: THIS LILLY HUMAN INSULIN ANALOG MIXTURE IS DIFFERENT FROM OTHER INSULIN MIXTURES IN THAT ITS ONSET OF ACTION IS VERY QUICK. THE QUICK ONSET OF ACTION MEANS THAT YOU SHOULD TAKE YOUR DOSE OF HUMALOG® Mix75/25™ (75% INSULIN LISPRO PROTAMINE SUSPENSION AND 25% INSULIN LISPRO INJECTION, [rDNA ORIGIN]) WITHIN 15 MINUTES BEFORE YOU EAT.

ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUSLY AND ONLY UNDER MEDICAL SUPERVISION. CHANGES IN STRENGTH, MANUFACTURER, TYPE (E.G., REGULAR, NPH, ANALOG), 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 Mix75/25.

PATIENTS TAKING HUMALOG Mix75/25 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.

HUMALOG® Mix75/25™ Pen 75% INSULIN LISPRO PROTAMINE
SUSPENSION AND 25% INSULIN LISPRO INJECTION (rDNA ORIGIN)

PV 3720 AMP

TO OBTAIN AN ACCURATE DOSE, CAREFULLY READ AND FOLLOW THE “DISPOSABLE INSULIN DELIVERY DEVICE USER MANUAL” AND THIS “INFORMATION FOR THE PATIENT” INSERT BEFORE USING THIS PRODUCT.

BEFORE EACH INJECTION, YOU SHOULD PRIME THE PEN, A NECESSARY STEP TO MAKE SURE THE PEN IS READY TO DOSE. PRIMING THE PEN IS IMPORTANT TO CONFIRM THAT INSULIN COMES OUT WHEN YOU PUSH THE INJECTION BUTTON AND TO REMOVE AIR THAT MAY COLLECT IN THE INSULIN CARTRIDGE DURING NORMAL USE. IF YOU DO NOT PRIME, YOU MAY RECEIVE TOO MUCH OR TOO LITTLE INSULIN (*see also* INSTRUCTIONS FOR INSULIN PEN 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 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, bedtime glucose levels are consistently above 160 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-targeted 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 Humalog Mix75/25 Pen as well as a spare needle on hand. Always wear diabetic identification so that appropriate treatment can be given if complications occur away from home.

HUMALOG® Mix75/25™ Pen 75% INSULIN LISPRO PROTAMINE
SUSPENSION AND 25% INSULIN LISPRO INJECTION (rDNA ORIGIN)

PV 3720 AMP

HUMALOG Mix75/25: 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 Mix75/25 is a mixture of 75% insulin lispro protamine suspension and 25% insulin lispro. It is a longer-acting insulin combined with the more rapid onset of action of Humalog. The duration of activity is similar to that of Humulin® 70/30 and may last up to 24 hours following injection. The time course of Humalog Mix75/25 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. Humalog Mix75/25 is a sterile suspension and is for subcutaneous injection. It should not be used intravenously. The concentration of Humalog Mix75/25 is 100 units/mL (U-100).

Humalog Mix75/25 starts lowering blood glucose more quickly than regular human insulin, allowing for convenient dosing immediately before a meal (within 15 minutes). In contrast, mixtures containing regular human insulin should be given 30 to 60 minutes before a meal.

Identification—Insulin lispro (rDNA origin) injection, by Eli Lilly and Company, has the trademark Humalog. **Humalog products are available in two formulations**—Humalog and Humalog Mix75/25. 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. YOU SHOULD NOT MIX HUMALOG Mix75/25 WITH ANOTHER INSULIN.

The Humalog Mix75/25 Pen is available in boxes of 5 disposable insulin delivery devices ("insulin Pens"). The Humalog Mix75/25 Pen is not designed to allow any other insulin to be mixed in its cartridge of Humalog Mix75/25, or for the cartridge to be removed.

Always examine the appearance of Humalog Mix75/25 suspension in the insulin Pen before administering a dose. Roll the Pen between the palms 10 times (see Figure 1). Holding the Pen by one end, invert it 180° slowly 10 times to allow the small glass bead to travel the full length of the cartridge with each inversion (see Figure 2).

HUMALOG® Mix75/25™ Pen 75% INSULIN LISPRO PROTAMINE
SUSPENSION AND 25% INSULIN LISPRO INJECTION (rDNA ORIGIN)

PV 3720 AMP



Figure 1.



Figure 2.

Humalog Mix75/25 should look uniformly cloudy or milky after mixing. If not, repeat the above steps until the contents are mixed. Pens containing Humalog Mix75/25 suspension should be examined frequently. Do not use if the insulin substance (the white material) remains visibly separated from the liquid after mixing. Do not use a Humalog Mix75/25 Pen if there are clumps in the insulin after mixing. Do not use a Humalog Mix75/25 Pen if solid white particles stick to the bottom or wall of the cartridge, giving a frosted appearance. Always check the appearance of the Humalog Mix75/25 suspension before using. If you note anything unusual in its appearance or notice your insulin requirements changing markedly, consult your doctor.

Storage—Not in-use (unopened)—Humalog Mix75/25 Pens not in-use should be stored in a refrigerator but not in the freezer. Do not use Humalog Mix75/25 Pen if it has been frozen.

In-use—Humalog Mix75/25 Pens in-use should **NOT** be refrigerated but should be kept at room temperature (below 86°F [30°C]) away from direct heat and light. Humalog Mix75/25 Pens in-use must be discarded **after 10 days**, even if they still contain Humalog Mix75/25.

Do not use Humalog Mix75/25 Pens after the expiration date stamped on the label.

HUMALOG® Mix75/25™ Pen 75% INSULIN LISPRO PROTAMINE
SUSPENSION AND 25% INSULIN LISPRO INJECTION (rDNA ORIGIN)

PV 3720 AMP

INSTRUCTIONS FOR INSULIN PEN USE: It is important to read, understand, and follow the instructions in the “Disposable Insulin Delivery Device User Manual” before using. Failure to follow instructions may result in getting too much or too little insulin. The needle must be changed and the Pen must be primed before each injection to make sure the Pen is ready to dose. Performing these steps before each injection is important to confirm that insulin comes out when you push the injection button, and to remove air that may collect in the insulin cartridge during normal use.

Every time you inject:

- Use a new needle.
- Prime to make sure the Pen is ready to dose.
- Make sure you got your full dose.

NEVER SHARE INSULIN PENS, CARTRIDGES, OR NEEDLES.

PREPARING THE INSULIN PEN FOR INJECTION:

1. Inspect the appearance of Humalog Mix75/25 suspension in the Humalog Mix75/25 Pen. It should look uniformly cloudy or milky after mixing. Once the Humalog Mix75/25 Pen is in use, inspect the insulin in the Humalog Mix75/25 Pen before each injection.
2. Follow the instructions in the “Disposable Insulin Delivery Device User Manual” for these steps:
 - Preparing the Pen
 - Attaching the Needle. **Use a new needle for each injection.**
 - Priming the Pen. **The Pen must be primed before each injection to make sure the Pen is ready to dose.** Performing the priming step is important to confirm that insulin comes out when you push the injection button, and to remove air that may collect in the insulin cartridge during normal use.
 - Setting a Dose
 - Injecting a Dose. **To make sure you have received your full dose, you must push the injection button all the way down until you see a diamond (◆) or an arrow (→) in the center of the dose window.**
 - Following an Injection

HUMALOG® Mix75/25™ Pen 75% INSULIN LISPRO PROTAMINE
SUSPENSION AND 25% INSULIN LISPRO INJECTION (rDNA ORIGIN)

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PREPARING FOR INJECTION

1. Wash your hands.
2. To avoid tissue damage, choose a site for each injection that is at least 1/2 inch from the previous injection site. The usual sites of injection are abdomen, thighs, and arms.
3. Cleanse the skin with alcohol where the injection is to be made.
4. With one hand, stabilize the skin by spreading it or pinching up a large area.
5. Inject the dose as instructed by your doctor. Hold the needle under the skin for at least 5 seconds after injecting.
6. After injecting a dose, pull the needle out and apply gentle pressure over the injection site for several seconds. **Do not rub the area.**
7. Immediately after an injection, remove the needle from the Humalog Mix75/25 Pen. Doing so will guard against contamination, and prevent leakage of Humalog Mix75/25, reentry of air, and needle clogs. **Do not reuse needles.** Place the used needle in a puncture resistant disposable container and properly dispose of it as directed by your Health Care Professional.

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 Mix75/25 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 Mix75/25 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 Mix75/25 has not been tested in pregnant or nursing women.

HUMALOG® Mix75/25™ Pen 75% INSULIN LISPRO PROTAMINE
SUSPENSION AND 25% INSULIN LISPRO INJECTION (rDNA ORIGIN)

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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 these and 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 Humalog Mix75/25 dose, especially if the exercise involves the area of your 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, stomach pains, 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.

HUMALOG® Mix75/25™ Pen 75% INSULIN LISPRO PROTAMINE
SUSPENSION AND 25% INSULIN LISPRO INJECTION (rDNA ORIGIN)

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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 Mix75/25 and Humalog Mix75/25 Pens can be obtained by calling The Lilly Answers Center at 1-800-LillyRx (1-800-545-5979).

Literature revised March 3, 2005

PV 3720 AMP



Eli Lilly and Company
Indianapolis, IN 46285, USA

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HUMALOG® Mix75/25™ Pen 75% INSULIN LISPRO PROTAMINE
SUSPENSION AND 25% INSULIN LISPRO INJECTION (rDNA ORIGIN)

PV 3720 AMP

INFORMATION FOR THE PATIENT

3 ML DISPOSABLE INSULIN DELIVERY DEVICE

HUMALOG® Mix50/50™ Pen 50% INSULIN LISPRO PROTAMINE SUSPENSION AND 50% INSULIN LISPRO INJECTION (rDNA ORIGIN) 100 UNITS PER ML (U-100)

WARNINGS: THIS LILLY HUMAN INSULIN ANALOG MIXTURE IS DIFFERENT FROM OTHER INSULIN MIXTURES IN THAT ITS ONSET OF ACTION IS VERY QUICK. THE QUICK ONSET OF ACTION MEANS THAT YOU SHOULD TAKE YOUR DOSE OF HUMALOG® Mix50/50™ (50% INSULIN LISPRO PROTAMINE SUSPENSION AND 50% INSULIN LISPRO INJECTION, [rDNA ORIGIN]) WITHIN 15 MINUTES BEFORE YOU EAT.

ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUSLY AND ONLY UNDER MEDICAL SUPERVISION. CHANGES IN STRENGTH, MANUFACTURER, TYPE (E.G., REGULAR, NPH, ANALOG), 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 Mix50/50.

PATIENTS TAKING HUMALOG Mix50/50 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.

TO OBTAIN AN ACCURATE DOSE, CAREFULLY READ AND FOLLOW THE “DISPOSABLE INSULIN DELIVERY DEVICE USER MANUAL” AND THIS “INFORMATION FOR THE PATIENT” INSERT BEFORE USING THIS PRODUCT. BEFORE EACH INJECTION, YOU SHOULD PRIME THE PEN, A NECESSARY STEP TO MAKE SURE THE PEN IS READY TO DOSE. PRIMING THE PEN IS IMPORTANT TO CONFIRM THAT INSULIN COMES OUT

Pen 50% INSULIN LISPRO PROTAMINE SUSPENSION AND 50% INSULIN LISPRO INJECTION (rDNA ORIGIN) PV 4511 AMP

WHEN YOU PUSH THE INJECTION BUTTON AND TO REMOVE AIR THAT MAY COLLECT IN THE INSULIN CARTRIDGE DURING NORMAL USE. IF YOU DO NOT PRIME, YOU MAY RECEIVE TOO MUCH OR TOO LITTLE INSULIN (*see also* INSTRUCTIONS FOR INSULIN PEN 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 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 premeal glucose levels are consistently above 130 mg/dL, bedtime glucose levels are consistently above 160 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-targeted 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 Humalog Mix50/50 Pen as well as a spare needle on hand. Always wear diabetic identification so that appropriate treatment can be given if complications occur away from home.

HUMALOG Mix50/50: Description—Humalog (insulin lispro [rDNA origin]) is made by a special non-disease-producing laboratory strain of *Escherichia coli* bacteria that has been

Pen 50% INSULIN LISPRO PROTAMINE SUSPENSION AND 50% INSULIN LISPRO INJECTION (rDNA ORIGIN) PV 4511 AMP

genetically altered by the addition of the gene for this human insulin analog. Humalog Mix50/50 is a mixture of 50% insulin lispro protamine suspension and 50% insulin lispro. It is a longer-acting insulin combined with the more rapid onset of action of Humalog. The duration of activity is similar to that of Humulin 50/50 and may last up to 16 hours following injection. The time course of Humalog Mix50/50 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. Humalog Mix50/50 is a sterile suspension and is for subcutaneous injection. It should not be used intravenously. The concentration of Humalog Mix50/50 is 100 units/mL (U-100).

Humalog Mix50/50 starts lowering blood glucose more quickly than regular human insulin, allowing for convenient dosing immediately before a meal (within 15 minutes). In contrast, mixtures containing regular human insulin should be given 30-60 minutes before a meal.

Identification—Insulin lispro (rDNA origin) injection, by Eli Lilly and Company, has the trademark Humalog. Humalog products are available in three formulations—Humalog, Humalog® Mix75/25™ and Humalog Mix50/50. 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. YOU SHOULD NOT MIX HUMALOG Mix50/50 WITH ANOTHER INSULIN.

The Humalog Mix50/50 Pen is available in boxes of 5 disposable insulin delivery devices ("insulin Pens"). The Humalog Mix50/50 Pen is not designed to allow any other insulin to be mixed in its cartridge of Humalog Mix50/50, or for the cartridge to be removed.

Always examine the appearance of Humalog Mix50/50 suspension in the insulin Pen before administering a dose. Roll the Pen between the palms 10 times (see Figure 1). Holding the Pen by one end, invert it 180° slowly 10 times to allow the glass bead to travel the full length of the cartridge with each inversion (see Figure 2).

Pen 50% INSULIN LISPRO PROTAMINE SUSPENSION AND 50% INSULIN LISPRO INJECTION (rDNA ORIGIN)
PV 4511 AMP



Figure 1.



Figure 2.

Humalog Mix50/50 should look uniformly cloudy or milky after mixing. If not, repeat the above steps until the contents are mixed. Pens containing Humalog Mix50/50 suspension should be examined frequently. Do not use if the insulin substance (the white material) remains visibly separated from the liquid after mixing. Do not use a Humalog Mix50/50 Pen if there are clumps in the insulin after mixing. Do not use a Humalog Mix50/50 Pen if solid white particles stick to the bottom or wall of the cartridge, giving a frosted appearance. Always check the appearance of the Humalog Mix50/50 suspension before using. If you note anything unusual in its appearance or notice your insulin requirements changing markedly, consult your doctor.

Storage—Not in-use (unopened): Humalog Mix50/50 Pens not in-use should be stored in a refrigerator but not in the freezer. Do not use Humalog Mix50/50 Pen if it has been frozen.

In-use: Humalog Mix50/50 Pens in-use should **NOT** be refrigerated but should be kept at room temperature (below 86°F [30°C]) away from direct heat and light. Humalog Mix50/50 Pens in-use must be discarded **after 10 days**, even if they still contain Humalog Mix50/50.

Do not use Humalog Mix50/50 Pens after the expiration date stamped on the label.

Pen 50% INSULIN LISPRO PROTAMINE SUSPENSION AND 50% INSULIN LISPRO INJECTION (rDNA ORIGIN)
PV 4511 AMP

INSTRUCTIONS FOR INSULIN PEN USE: It is important to read, understand, and follow the instructions in the “Disposable Insulin Delivery Device User Manual” before using. Failure to follow instructions may result in getting too much or too little insulin. The needle must be changed and the Pen must be primed before each injection to make sure the Pen is ready to dose. Performing the priming step is important to confirm that insulin comes out when you push the injection button, and to remove air that may collect in the insulin cartridge during normal use.

Every time you inject:

- Use a new needle.
- Prime to make sure the Pen is ready to dose.
- Make sure you got your full dose.

NEVER SHARE INSULIN PENS, CARTRIDGES, OR NEEDLES.

PREPARING THE INSULIN PEN FOR INJECTION

1. Inspect the appearance of Humalog Mix50/50 suspension in the Humalog Mix50/50 Pen. It should look uniformly cloudy or milky after mixing. Once the Humalog Mix50/50 Pen is in use, inspect the insulin in the Humalog Mix50/50 Pen before each injection.
2. Follow the instructions in the “Disposable Insulin Delivery Device User Manual” for these steps:
 - Preparing the Pen
 - Attaching the Needle. **Use a new needle for each injection.**
 - Priming the Pen. **The Pen must be primed before each injection to make sure the Pen is ready to dose.** Performing the priming step is important to confirm that insulin comes out when you push the injection button, and to remove air that may collect in the insulin cartridge during normal use.
 - Setting a Dose
 - Injecting a Dose. **To make sure you have received your full dose, you must push the injection button all the way down until you see a diamond (◆) or an arrow (→) in the center of the dose window.**
 - Following an Injection

Pen 50% INSULIN LISPRO PROTAMINE SUSPENSION AND 50% INSULIN LISPRO INJECTION (rDNA ORIGIN)
PV 4511 AMP

PREPARING FOR INJECTION

1. Wash your hands.
2. To avoid tissue damage, choose a site for each injection that is at least 1/2 inch from the previous injection site. The usual sites of injection are abdomen, thighs, and arms.
3. Cleanse the skin with alcohol where the injection is to be made.
4. With one hand, stabilize the skin by spreading it or pinching up a large area.
5. Inject the dose as instructed by your doctor. Hold the needle under the skin for at least 5 seconds after injecting.
6. After injecting a dose, pull the needle out and apply gentle pressure over the injection site for several seconds. **Do not rub the area.**
7. Immediately after an injection, remove the needle from the Humalog Mix50/50 Pen. Doing so will guard against contamination, and prevent leakage of Humalog Mix50/50, reentry of air, and needle clogs. **Do not reuse needles.** Place the used needle in a puncture-resistant disposable container and properly dispose of it as directed by your Health Care Professional.

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 Mix50/50 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 Mix50/50 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 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 Mix50/50 has not been tested in pregnant or nursing women.

Pen 50% INSULIN LISPRO PROTAMINE SUSPENSION AND 50% INSULIN LISPRO INJECTION (rDNA ORIGIN)
PV 4511 AMP

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 these and 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 Humalog Mix50/50 dose, especially if the exercise involves the area of your 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.

Pen 50% INSULIN LISPRO PROTAMINE SUSPENSION AND 50% INSULIN LISPRO INJECTION (rDNA ORIGIN)
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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.

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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, stomach pains, 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 lipodystrophy (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.

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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 Mix50/50 and Humalog Mix50/50 Pens can be obtained by calling The Lilly Answers Center at 1-800-LillyRx (1-800-545-5979).

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Humalog, Humalog Mix75/25, and Humalog Mix50/50 are for use in patients with diabetes to control high blood sugar. Humalog should be used with a longer-acting insulin, except when used in combination with sulfonylureas in patients with type 2 diabetes.

Important Safety Information

Humalog insulins are contraindicated during episodes of hypoglycemia and in patients sensitive to Humalog or one of its excipients. The safety and effectiveness of Humalog in patients less than 3 years of age have not been established. Safety and effectiveness of Humalog Mix75/25 and Humalog Mix50/50 in Patients less than 18 years of age have not been established. There are no clinical studies of the use of Humalog insulins in pregnancy or nursing mothers.

Potential side effects associated with the use of all insulins include low blood sugar, weight gain, low blood potassium, changes in fat tissue at the site of injection, and allergic reactions, both general and local.

Humalog Mix75/25 and Humalog Mix50/50 should not be mixed with another insulin. Starting or changing insulin therapy should be done cautiously and only under medical supervision.

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