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**INFORMATION FOR THE PATIENT  
3 ML DISPOSABLE INSULIN DELIVERY DEVICE**

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**HUMALOG<sup>®</sup> Pen  
INSULIN LISPRO INJECTION  
(rDNA ORIGIN)  
100 UNITS PER ML (U-100)**

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**WARNINGS**

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**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<sup>®</sup> (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.**

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**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.**

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**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.**

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**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.**

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**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).**

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**DIABETES**

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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.

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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

48 urine regularly for glucose. Studies have shown that some chronic complications of diabetes  
 49 such as eye disease, kidney disease, and nerve disease can be significantly reduced if the blood  
 50 sugar is maintained as close to normal as possible. The American Diabetes Association  
 51 recommends that if your pre-meal glucose levels are consistently above 130 mg/dL or your  
 52 hemoglobin A<sub>1c</sub> (HbA<sub>1c</sub>) is more than 7%, consult your doctor. A change in your diabetes  
 53 therapy may be needed. If your blood tests consistently show below-normal glucose levels you  
 54 should also let your doctor know. Proper control of your diabetes requires close and constant  
 55 cooperation with your doctor. Despite diabetes, you can lead an active and healthy life if you eat  
 56 a balanced diet, exercise regularly, and take your insulin injections as prescribed.

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

## 60 HUMALOG

### 61 Description

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

### 76 Identification

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

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

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

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

### 89 Storage

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

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

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

## 96 INSTRUCTIONS FOR INSULIN PEN USE

97 **It is important to read, understand, and follow the instructions in the "Disposable Insulin**  
 98 **Delivery Device User Manual" before using. Failure to follow instructions may result in**

99 **getting too much or too little insulin. The needle must be changed and the Pen must be**  
 100 **primed before each injection to make sure the Pen is ready to dose. Performing these steps**  
 101 **before each injection is important to confirm that insulin comes out when you push the**  
 102 **injection button, and to remove air that may collect in the insulin cartridge during normal**  
 103 **use.**

104 **Every time you inject:**

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

108 **NEVER SHARE INSULIN PENS, CARTRIDGES, OR NEEDLES.**

### 109 **PREPARING THE INSULIN PEN FOR INJECTION**

- 110 1. Inspect the appearance of Humalog solution in the Humalog Pen. It should look clear and  
 111 colorless. Do not use Humalog if it appears cloudy, thickened, or slightly colored, or if  
 112 solid particles are visible.
- 113 2. Follow the instructions in the “Disposable Insulin Delivery Device User Manual” for  
 114 these steps:
  - 115 • Preparing the Pen
  - 116 • Attaching the Needle. **Use a new needle for each injection.**
  - 117 • Priming the Pen. **The Pen must be primed before each injection to make sure the**  
 118 **Pen is ready to dose.** Performing the priming step is important to confirm that insulin  
 119 comes out when you push the injection button, and to remove air that may collect in the  
 120 insulin cartridge during normal use.
  - 121 • Setting a Dose
  - 122 • Injecting a Dose. **To make sure you have received your full dose, you must push the**  
 123 **injection button all the way down until you see a diamond (◆) or an arrow (→) in**  
 124 **the center of the dose window.**
  - 125 • Following an Injection

### 126 **PREPARING FOR INJECTION**

- 127 1. Wash your hands.
- 128 2. To avoid tissue damage, choose a site for each injection that is at least 1/2 inch from the  
 129 previous injection site. The usual sites of injection are abdomen, thighs, and arms.
- 130 3. Cleanse the skin with alcohol where the injection is to be made.
- 131 4. With one hand, stabilize the skin by spreading it or pinching up a large area.
- 132 5. Inject the dose as instructed by your doctor. Hold the needle under the skin for at least  
 133 5 seconds after injecting.
- 134 6. After injecting a dose, pull the needle out and apply gentle pressure over the injection site  
 135 for several seconds. **Do not rub the area.**
- 136 7. Immediately after an injection, remove the needle from the Humalog Pen. Doing so will  
 137 guard against contamination, and prevent leakage of Humalog, reentry of air, and needle  
 138 clogs. **Do not reuse needles.** Place the used needle in a puncture-resistant disposable  
 139 container and properly dispose of it as directed by your Health Care Professional.

### 140 **DOSAGE**

141 Your doctor has told you which insulin to use, how much, and when and how often to inject it.  
 142 Because each patient’s diabetes is different, this schedule has been individualized for you. Your  
 143 usual dose of Humalog may be affected by changes in your food, activity, or work schedule.  
 144 Carefully follow your doctor’s instructions to allow for these changes. Other things that may  
 145 affect your dose of Humalog are:

#### 146 **Illness**

147 Illness, especially with nausea and vomiting, may cause your insulin requirements to change.  
 148 Even if you are not eating, you will still require insulin. You and your doctor should establish a

149 sick day plan for you to use in case of illness. When you are sick, test your blood glucose/urine  
150 glucose and ketones frequently and call your doctor as instructed.

### 151 **Pregnancy**

152 Good control of diabetes is especially important for you and your unborn baby. Pregnancy may  
153 make managing your diabetes more difficult. If you are planning to have a baby, are pregnant, or  
154 are nursing a baby, consult your doctor. Humalog has not been tested in pregnant or nursing  
155 women.

### 156 **Geriatric Use**

157 Elderly patients using Humalog had HbA<sub>1c</sub> values and hypoglycemia rates similar to those  
158 observed in younger patients. The onset of action of Humalog may be different in elderly  
159 patients.

### 160 **Medication**

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

### 168 **Exercise**

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

### 173 **Travel**

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

## 176 **COMMON PROBLEMS OF DIABETES**

### 177 **Hypoglycemia (Low Blood Sugar)**

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

- 180 1. **Missing or delaying meals.**
- 181 2. Taking too much insulin.
- 182 3. Exercising or working more than usual.
- 183 4. An infection or illness (especially with diarrhea or vomiting).
- 184 5. A change in the body's need for insulin.
- 185 6. Diseases of the adrenal, pituitary, or thyroid gland, or progression of kidney or liver  
186 disease.
- 187 7. Interactions with other drugs that lower blood glucose, such as oral antidiabetic agents,  
188 salicylates (for example, aspirin), sulfa antibiotics, and certain antidepressants.
- 189 8. Consumption of alcoholic beverages.

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

- |  |                      |
|--|----------------------|
| 191 • sweating                                     | • drowsiness         |
| 192 • dizziness                                    | • sleep disturbances |
| 193 • palpitation                                  | • anxiety            |
| 194 • tremor                                       | • blurred vision     |
| 195 • hunger                                       | • slurred speech     |
| 196 • restlessness                                 | • depressed mood     |
| 197 • tingling in the hands, feet, lips, or tongue | • irritability       |
| 198 • lightheadedness                              | • abnormal behavior  |

- 199 • inability to concentrate
- 200 • headache
- 201 Signs of severe hypoglycemia can include:
- 202 • disorientation
- 203 • unconsciousness
- unsteady movement
- personality changes
- seizures
- death

204 Therefore, it is important that assistance be obtained immediately.

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

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

218 Mild to moderate hypoglycemia may be treated by eating foods or drinks that contain sugar.  
 219 Patients should always carry a quick source of sugar, such as candy mints or glucose tablets.  
 220 More severe hypoglycemia may require the assistance of another person. Patients who are unable  
 221 to take sugar orally or who are unconscious require an injection of glucagon or should be treated  
 222 with intravenous administration of glucose at a medical facility.

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

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

### 229 **Hyperglycemia and Diabetic Ketoacidosis (DKA)**

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

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

235 In patients with type 1 or insulin-dependent diabetes, prolonged hyperglycemia can result in  
 236 DKA. The first symptoms of DKA usually come on gradually, over a period of hours or days,  
 237 and include a drowsy feeling, flushed face, thirst, loss of appetite, and fruity odor on the breath.  
 238 With DKA, urine tests show large amounts of glucose and ketones. Heavy breathing and a rapid  
 239 pulse are more severe symptoms. If uncorrected, prolonged hyperglycemia or DKA can lead to  
 240 nausea, vomiting, stomach pains, dehydration, loss of consciousness, or death. Therefore, it is  
 241 important that you obtain medical assistance immediately.

### 242 **Lipodystrophy**

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

### 247 **Allergy**

248 *Local Allergy* — Patients occasionally experience redness, swelling, and itching at the site of  
 249 injection. This condition, called local allergy, usually clears up in a few days to a few weeks. In

250 some instances, this condition may be related to factors other than insulin, such as irritants in the  
251 skin cleansing agent or poor injection technique. If you have local reactions, contact your doctor.

252 *Systemic Allergy* — Less common, but potentially more serious, is generalized allergy to  
253 insulin, which may cause rash over the whole body, shortness of breath, wheezing, reduction in  
254 blood pressure, fast pulse, or sweating. Severe cases of generalized allergy may be life  
255 threatening. If you think you are having a generalized allergic reaction, notify a doctor  
256 immediately.

#### 257 **ADDITIONAL INFORMATION**

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

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

262 Another publication, **COUNTDOWN**, is available from the Juvenile Diabetes Research  
263 Foundation International (JDRFI), 120 Wall Street 19th Floor, New York, NY 10005,  
264 1-800-533-CURE (1-800-533-2873).

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

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270 for Eli Lilly and Company  
271 Indianapolis, IN 46285, USA

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**Lilly**  
**Disposable Insulin Delivery Device**  
**User Manual**

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**Instructions for Use**

Read and follow all of these instructions carefully. If you do not follow these instructions completely, you may get too much or too little insulin.

**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 (see page 18)



Also, read the *Information for the Patient* insert enclosed in your Pen box.

**Pen Features**

- A multiple dose, disposable insulin delivery device (“insulin Pen”) containing 3 mL (300 units) of U-100 insulin
  - Delivers up to 60 units per dose
  - Doses can be dialed by single units
-

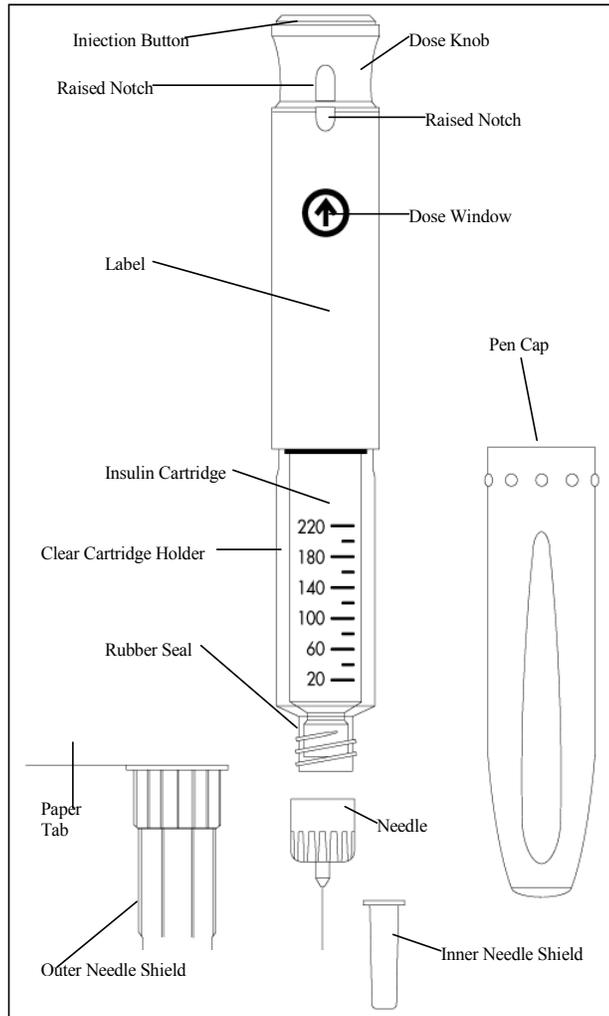
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### Pen Parts



### Important Notes

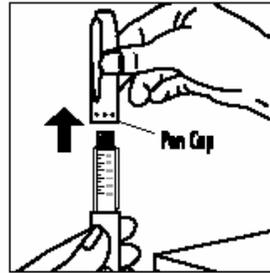
- **Read and follow all of these instructions carefully. If you do not follow these instructions completely, you may get too much or too little insulin.**
- **Use a new needle for each injection.**
  - **Be sure a needle is completely attached to the Pen before priming, setting the dose and injecting your insulin.**
- **Prime every time.**
  - **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. **See Section III. “Priming the Pen”, pages 10-13.**
  - **If you do not prime, you may get too much or too little insulin.**
  - **Make sure you get your full dose.**
    - To make sure you get 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. See “Following an Injection”, page 18.
- The numbers on the clear cartridge holder give an estimate of the amount of insulin remaining in the cartridge. Do not use these numbers for measuring an insulin dose.
- Do not share your Pen.
- Keep your Pen out of the reach of children.
- Pens that have not been used (unopened) should be stored in a refrigerator but not in a freezer. Do not use a Pen if it has been frozen. Refer to the INFORMATION FOR THE PATIENT insert for complete storage instructions.

### Important Notes (Continued)

- After a Pen is used for the first time, it should **NOT** be refrigerated but should be kept at room temperature [below 86°F (30°C)] and away from direct heat and light.
- An unrefrigerated Pen should be discarded according to the time specified in the *Information for the Patient* insert, even if it still contains insulin.
- Never use a Pen after the expiration date stamped on the label.
- Do not store your Pen with the needle attached. Doing so may allow insulin to leak from the Pen and air bubbles to form in the cartridge. Additionally, with suspension (cloudy) insulins, crystals may clog the needle.
- Always carry an extra Pen in case yours is lost or damaged.
- Dispose of empty Pens as instructed by your Health Care Professional and without the needle attached.
- This Pen is not recommended for use by blind or visually impaired persons without the assistance of a person trained in the proper use of the product.
- The directions regarding needle handling are not intended to replace local, Health Care Professional, or institutional policies.
- **Any changes in insulin should be made cautiously and only under medical supervision.**

### I. Preparing the Pen

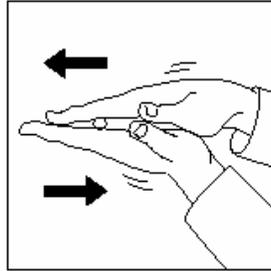
1. Before proceeding, refer to the INFORMATION FOR THE PATIENT insert for instructions on checking the appearance of your insulin.
2. Check the label on the Pen to be sure the Pen contains the type of insulin that has been prescribed for you.
3. Always wash your hands before preparing your Pen for use.
4. Pull the Pen cap to remove.



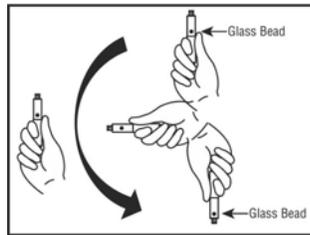
### I. Preparing the Pen (Continued)

5. If your insulin is a suspension (cloudy):

- a. Roll the Pen back and forth 10 times then perform step b.

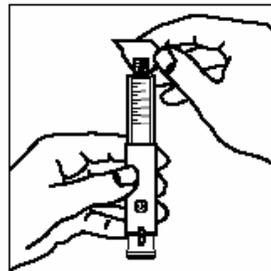


- b. Gently turn the Pen up and down 10 times until the insulin is evenly mixed.



**Note:** Suspension (cloudy) insulin cartridges contain a small glass bead to assist in mixing.

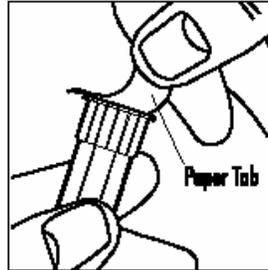
6. Use an alcohol swab to wipe the rubber seal on the end of the Pen.



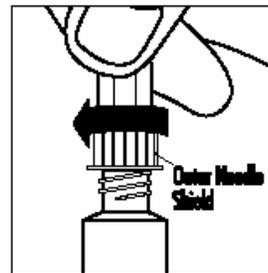
## II. Attaching the Needle

This device is suitable for use with Becton Dickinson and Company's insulin pen needles.

1. Always use a new needle for each injection. Do not push injection button without a needle attached. Storing the Pen with the needle attached may allow insulin to leak from the Pen and air bubbles to form in the cartridge.
2. Remove the paper tab from the outer needle shield.

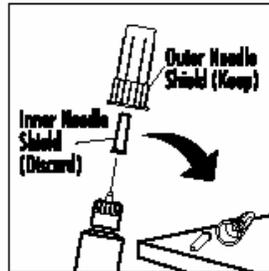


3. Attach the capped needle onto the end of the Pen by turning it clockwise until tight.



## II. Attaching the Needle (Continued)

4. Hold the Pen with the needle pointing up and remove the **outer needle shield**. **Keep it to use during needle removal.**

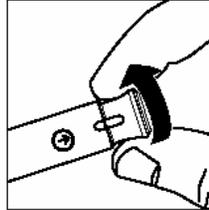


5. Remove the inner needle shield and discard.

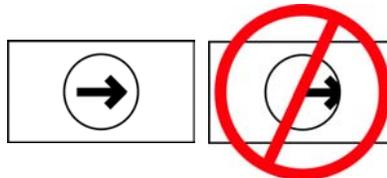
### III. Priming the Pen

- **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.
- **If you do not prime, you may get too much or too little insulin.**
- **Always use a new needle for each injection.**

1. Make sure the arrow is in the center of the dose window as shown.



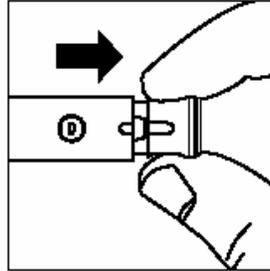
2. If you do not see the arrow in the center of the dose window, push in the injection button fully and turn the dose knob until the arrow is seen in the center of the dose window.



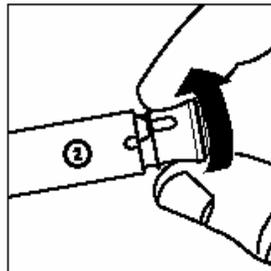
Correct

### III. Priming the Pen (Continued)

3. With the arrow in the center of the dose window, pull the dose knob out in the direction of the arrow until a "0" is seen in the dose window.



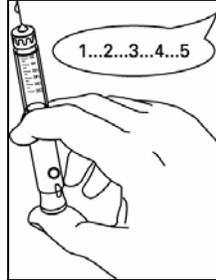
4. Turn the dose knob clockwise until the number "2" is seen in the dose window. If the number you have dialed is too high, simply turn the dose knob backward until the number 2 is seen in the dose window.



### III. Priming the Pen (Continued)

5. Hold your Pen with the needle pointing up. Tap the clear cartridge holder gently with your finger so any air bubbles collect near the top.

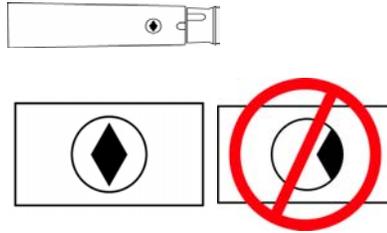
Using your thumb, if possible, push in the injection button completely. Keep pressing and continue to hold the injection button **firmly** while counting **slowly** to 5. You should see either a drop or a stream of insulin come out of the tip of the needle.



If insulin does not come out of the tip of the needle, repeat steps 1 through 5. If after several attempts insulin does not come out of the tip of the needle, change the needle and repeat the priming steps.

### III. Priming the Pen (Continued)

6. At the completion of the priming step, a diamond (◆) must be seen in the center of the dose window. If a diamond (◆) is not seen in the center of the dose window, continue pushing on the injection button until you see a diamond (◆) in the center of the dose window.



Correct

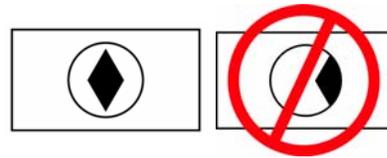
**Note:** A small air bubble may remain in the cartridge after the completion of the priming step. If you have properly primed the Pen, this small air bubble will not affect your insulin dose.

7. Now you are ready to set your dose. See next page.

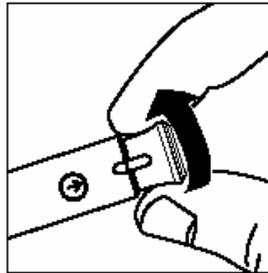
#### IV. Setting a Dose

- **Always use a new needle for each injection. Storing the Pen with the needle attached may allow insulin to leak from the Pen and air bubbles to form in the cartridge.**
  - **Caution: Do not push in the injection button while setting your dose. Failure to follow these instructions carefully may result in getting too much or too little insulin. If you accidentally push the injection button while setting your dose, you must prime the Pen again before injecting your dose. See Section III. “Priming the Pen”, pages 10-13.**
1. A diamond must be seen in the center of the dose window before setting your dose.

If you do not see a diamond in the center of the dose window, the Pen has not been primed correctly and you are not ready to set your dose. Before continuing, repeat the priming steps.

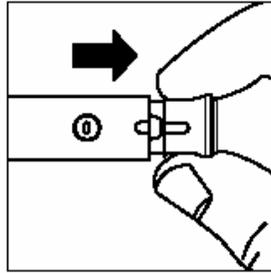


2. Turn the dose knob clockwise until the arrow (→) is seen in the center of the dose window and the notches on the Pen and dose knob are in line.

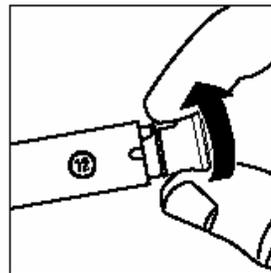


#### IV. Setting a Dose (Continued)

3. With the arrow (→) in the center of the dose window, pull the dose knob out in the direction of the arrow until a “0” is seen in the dose window. A dose cannot be dialed until the dose knob is pulled out.



4. Turn the dose knob clockwise until your dose is seen in the dose window. If the dose you have dialed is too high, simply turn the dose knob backward until the correct dose is seen in the dose window.



5. If you cannot dial your full dose, see the “Questions and Answers” section, Question 5, at the end of this manual.

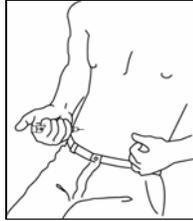
## V. Injecting a Dose

- **Always use a new needle for each injection. Storing the Pen with the needle attached may allow insulin to leak from the Pen and air bubbles to form in the cartridge.**
- **Caution: Do not attempt to change the dose after you begin to push in the injection button. Failure to follow these instructions carefully may result in getting too much or too little insulin.**
- **The effort needed to push in the injection button may increase while you are injecting your insulin dose. If you cannot completely push in the injection button, refer to the “Questions and Answers” section, Question 7, at the end of this manual.**
- Do not inject a dose unless the Pen is primed, just before injection, or you may get too much or too little insulin.
- If you have set a dose and pushed in the injection button without a needle attached or if no insulin comes out of the needle, see the “Questions and Answers” section, Questions 1 and 2.

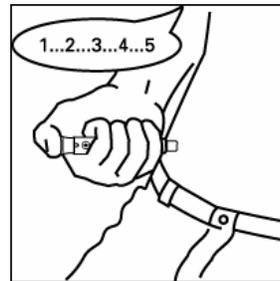
## V. Injecting a Dose (Continued)

1. Wash hands. Prepare the skin and use the injection technique recommended by your Health Care Professional.

2. Insert the needle into your skin. Inject the insulin by using your thumb, if possible, to push in the injection button completely.



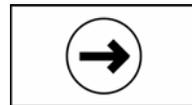
3. Keep pressing and continue to hold the injection button **firmly** while counting **slowly** to 5.



4. When the injection is done, a diamond (◆) or arrow (→) must be seen in the center of the dose window. This means your full dose has been delivered. **If you do not see the diamond or arrow in the center of the dose window, you did not get a full dose. Contact your Health Care Professional for additional instruction.**



Correct

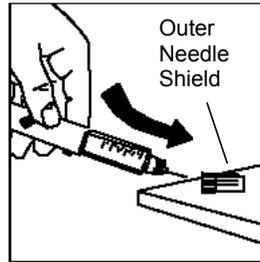


Correct



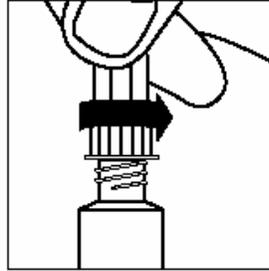
## VI. Following an Injection

1. Make sure you got your full dose by checking that the injection button has been completely pushed in and you can see a diamond (◆) or arrow (→) in the center of the dose window. If you do not see the diamond (◆) or arrow (→) in the center of the dose window, you have not received your full dose. Contact your Health Care Professional for additional instructions.
2. Carefully replace the **outer needle shield** as instructed by your Health Care Professional.

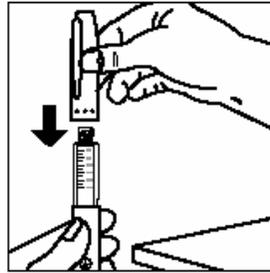


## VI. Following an Injection (Continued)

3. Remove the capped needle by turning it counterclockwise. Place the used needle in a puncture-resistant disposable container and properly throw it away as directed by your Health Care Professional.



4. Replace the cap on the Pen.



5. The Pen that you are currently using should be kept at a temperature below 86°F (30°C) and away from heat and light. It should be discarded according to the time specified in the INFORMATION FOR THE PATIENT insert, even if it still contains insulin.

**Do not store or dispose of the Pen with a needle attached. Storing the Pen with the needle attached may allow insulin to leak from the Pen and air bubbles to form in the cartridge.**

### Questions and Answers

Problem	Action
1. Dose dialed and injection button pushed in without a needle attached.	To obtain an accurate dose you must: <ol style="list-style-type: none"> <li>1) Attach a new needle.</li> <li>2) Push in the injection button completely (even if a "0" is seen in the window) until a diamond (◆) or arrow (→) is seen in the center of the dose window.</li> <li>3) Prime the Pen.</li> </ol>
2. Insulin does not come out of the needle.	To obtain an accurate dose you must: <ol style="list-style-type: none"> <li>1) Attach a new needle.</li> <li>2) Push in the injection button completely (even if a "0" is seen in the window) until a diamond (◆) or arrow (→) is seen in the center of the dose window.</li> <li>3) Prime the Pen. See Section III. "Priming the Pen", pages 10-13.</li> </ol>

**Questions and Answers  
(Continued)**

<b>Problem</b>	<b>Action</b>
3. Wrong dose (too high or too low) dialed.	If you have not pushed in the injection button, simply turn the dose knob backward or forward to correct the dose.
4. Not sure how much insulin remains in the cartridge.	Hold the Pen with the needle end pointing down. The scale (20 units between marks) on the clear cartridge holder shows an estimate of the number of units remaining. <b>These numbers should not be used for measuring an insulin dose.</b>

**Questions and Answers  
(Continued)**

<b>Problem</b>	<b>Action</b>
5. Full dose cannot be dialed.	<p>The Pen will not allow you to dial a dose greater than the number of insulin units remaining in the cartridge.</p> <p>For example, if you need 31 units and only 25 units remain in the Pen you will not be able to dial past 25. Do not attempt to dial past this point. (The insulin that remains is unusable and not part of the 300 units.) If a partial dose remains in the Pen you may either:</p> <ol style="list-style-type: none"><li>1) Give the partial dose and then give the remaining dose using a new Pen, or</li><li>2) Give the full dose with a new Pen.</li></ol>
6. A small amount of insulin remains in the cartridge but a dose cannot be dialed.	<p>The Pen design prevents the cartridge from being completely emptied. The Pen has delivered 300 units of usable insulin.</p>

**Questions and Answers  
(Continued)**

<b>Problem</b>	<b>Action</b>
7. Cannot completely push in the injection button when priming the Pen or injecting a dose.	<ol style="list-style-type: none"><li>1) Needle is not attached or is clogged.<ol style="list-style-type: none"><li>a. Attach a new needle.</li><li>b. Push in the injection button completely (even if a "0" is seen in the window) until a diamond (◆) or arrow (→) is seen in the center of the dose window.</li><li>c. Prime the Pen.</li></ol></li><li>2) If you are sure insulin is coming out of the needle, push in the injection button more slowly to reduce the effort needed and maintain a constant pressure until the injection button is completely pushed in.</li></ol>

**For additional information call,  
1-800-LILLY-RX (1-800-545-5979)**

Revised XX, 2004

Manufactured by Lilly France S.A.S.  
F-67640 Fegersheim, France  
for Eli Lilly and Company  
Indianapolis, IN 46285, USA

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PA 9115 FSAMP

**3 mL** *Lilly* 5 x 3 mL disposable insulin delivery devices  
**Humalog Pen**<sup>®</sup> 100 units per mL  
insulin lispro injection  
(rDNA origin)  
**U-100** HP 8725  
disposable insulin delivery device  
For information call 1-888-885-4559

*Lilly* 5 x 3 mL disposable insulin delivery devices  
NDC 0002-8725-59  
HP 8725  
100 Units per mL



# Humalog Pen<sup>®</sup>

insulin lispro injection  
(rDNA origin)

disposable insulin delivery device

**Important**  
Please read updated User Manual  
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

**U-100**



This device is suitable for use with Becton Dickinson and Company's insulin pen needles (needles not included)

**Rx only**

Control No. / Exp. Date



**3 mL** *Lilly* 5 x 3 mL disposable insulin delivery devices  
**Humalog Pen**<sup>®</sup> 100 units per mL  
insulin lispro injection (rDNA origin) **U-100**  
disposable insulin delivery device

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116,5-27,5-186,5  
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97 04 01 31

**If the seal is broken before first use, contact pharmacist**

**Keep in a cold place. Avoid freezing.**

**Warning:** Any change of insulin should be made cautiously and only under medical supervision.

**For subcutaneous use.**

See enclosed insert for dosage.

Each mL contains: 100 Units of insulin lispro: glycerin, 16 mg; dibasic sodium phosphate, 1.88 mg; Metacresol, 3.15 mg; zinc oxide content adjusted to provide 0.0197 mg zinc ion; trace amounts of phenol, and water for injection. Hydrochloric acid 10% and/or sodium hydroxide 10% may be added to adjust pH.

**Neutral**

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**IMPORTANT - SEE WARNINGS ON ENCLOSED INSERT**



3 0002-8725-59 7

**If the seal is broken before first use, contact pharmacist**

SH 8713 FSAMS

**3 mL** *Lilly* 5 x 3 mL disposable insulin delivery devices  
**Humalog Pen**<sup>®</sup> 100 units per mL  
insulin lispro injection (rDNA origin) **U-100**  
disposable insulin delivery device