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

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**HUMALOG[®] Mix75/25[™] Pen
75% INSULIN LISPRO PROTAMINE SUSPENSION AND
25% 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 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.

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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, 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.

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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.

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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 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

47 consistently above 160 mg/dL or your hemoglobin A_{1c} (HbA_{1c}) is more than 7%, consult your
 48 doctor. A change in your diabetes therapy may be needed. If your blood tests consistently show
 49 below-targeted glucose levels, you should also let your doctor know. Proper control of your
 50 diabetes requires close and constant cooperation with your doctor. Despite diabetes, you can lead
 51 an active and healthy life if you eat a balanced diet, exercise regularly, and take your insulin
 52 injections as prescribed.

53 Always keep an extra Humalog Mix75/25 Pen as well as a spare needle on hand. Always wear
 54 diabetic identification so that appropriate treatment can be given if complications occur away
 55 from home.

56 HUMALOG Mix75/25

57 Description

58 Humalog (insulin lispro [rDNA origin]) is made by a special non-disease-producing laboratory
 59 strain of *Escherichia coli* bacteria that has been genetically altered by the addition of the gene
 60 for this human insulin analog. Humalog Mix75/25 is a mixture of 75% insulin lispro protamine
 61 suspension and 25% insulin lispro. It is a longer-acting insulin combined with the more rapid
 62 onset of action of Humalog. The duration of activity is similar to that of Humulin[®] 70/30 and
 63 may last up to 24 hours following injection. The time course of Humalog Mix75/25 action, like
 64 that of other insulins, may vary in different individuals or at different times in the same
 65 individual, based on dose, site of injection, blood supply, temperature, and physical activity.
 66 Humalog Mix75/25 is a sterile suspension and is for subcutaneous injection. It should not be
 67 used intravenously. The concentration of Humalog Mix75/25 is 100 units/mL (U-100).

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

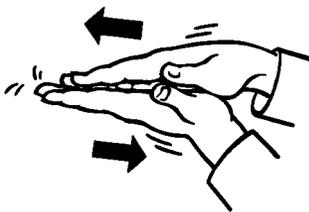
71 Identification

72 Insulin lispro ([rDNA origin](#)) injection (~~rDNA origin~~), by Eli Lilly and Company, has the
 73 trademark Humalog. Humalog products are available in two formulations — Humalog and
 74 Humalog Mix75/25. Your doctor has prescribed the type of insulin that he/she believes is best
 75 for you.

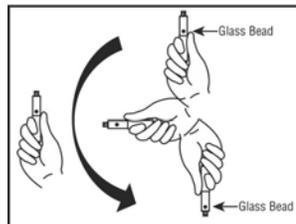
76 **DO NOT USE ANY OTHER INSULIN EXCEPT ON YOUR DOCTOR'S ADVICE AND**
 77 **DIRECTION. YOU SHOULD NOT MIX HUMALOG Mix75/25 WITH ANOTHER**
 78 **INSULIN.**

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

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



86 Figure 1.



87 Figure 2.

88 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

89 be examined frequently. Do not use if the insulin substance (the white material) remains visibly
 90 separated from the liquid after mixing. Do not use a Humalog Mix75/25 Pen if there are clumps
 91 in the insulin after mixing. Do not use a Humalog Mix75/25 Pen if solid white particles stick to
 92 the bottom or wall of the cartridge, giving a frosted appearance. Always check the appearance of
 93 the Humalog Mix75/25 suspension before using. If you note anything unusual in its appearance
 94 or notice your insulin requirements changing markedly, consult your doctor.

95 **Storage**

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

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

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

102 **INSTRUCTIONS FOR INSULIN PEN USE**

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

110 **Every time you inject:**

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

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

115 **PREPARING THE INSULIN PEN FOR INJECTION**

116 1. Inspect the appearance of Humalog Mix75/25 suspension in the Humalog Mix75/25 Pen.
 117 It should look uniformly cloudy or milky after mixing. Once the Humalog Mix75/25 Pen
 118 is in use, inspect the insulin in the Humalog Mix75/25 Pen before each injection.

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

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

132 **PREPARING FOR INJECTION**

- 133 1. Wash your hands.
- 134 2. To avoid tissue damage, choose a site for each injection that is at least 1/2 inch from the
 135 previous injection site. The usual sites of injection are abdomen, thighs, and arms.
- 136 3. Cleanse the skin with alcohol where the injection is to be made.
- 137 4. With one hand, stabilize the skin by spreading it or pinching up a large area.
- 138 5. Inject the dose as instructed by your doctor. Hold the needle under the skin for at least
 139 5 seconds after injecting.

- 140 6. After injecting a dose, pull the needle out and apply gentle pressure over the injection site
 141 for several seconds. **Do not rub the area.**
 142 7. Immediately after an injection, remove the needle from the Humalog Mix75/25 Pen.
 143 Doing so will guard against contamination, and prevent leakage of Humalog Mix75/25,
 144 reentry of air, and needle clogs. **Do not reuse needles.** Place the used needle in a
 145 puncture-resistant disposable container and properly dispose of it as directed by your
 146 Health Care Professional.

147 **DOSAGE**

148 Your doctor has told you which insulin to use, how much, and when and how often to inject it.
 149 Because each patient's case of diabetes is different, this schedule has been individualized for
 150 you. Your usual Humalog Mix75/25 dose may be affected by changes in your food, activity, or
 151 work schedule. Carefully follow your doctor's instructions to allow for these changes. Other
 152 things that may affect your Humalog Mix75/25 dose are:

153 **Illness**

154 Illness, especially with nausea and vomiting, may cause your insulin requirements to change.
 155 Even if you are not eating, you will still require insulin. You and your doctor should establish a
 156 sick day plan for you to use in case of illness. When you are sick, test your blood glucose/urine
 157 glucose and ketones frequently and call your doctor as instructed.

158 **Pregnancy**

159 Good control of diabetes is especially important for you and your unborn baby. Pregnancy may
 160 make managing your diabetes more difficult. If you are planning to have a baby, are pregnant, or
 161 are nursing a baby, consult your doctor. Humalog Mix75/25 has not been tested in pregnant or
 162 nursing women.

163 **Medication**

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

171 **Exercise**

172 Exercise may lower your body's need for insulin products during and for some time after the
 173 physical activity. Exercise may also speed up the effect of a Humalog Mix75/25 dose, especially
 174 if the exercise involves the area of your injection site. Discuss with your doctor how you should
 175 adjust your regimen to accommodate exercise.

176 **Travel**

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

179 **COMMON PROBLEMS OF DIABETES**

180 **Hypoglycemia (Low Blood Sugar)**

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

- 183 1. **Missing or delaying meals.**
- 184 2. Taking too much insulin.
- 185 3. Exercising or working more than usual.
- 186 4. An infection or illness (especially with diarrhea or vomiting).
- 187 5. A change in the body's need for insulin.
- 188 6. Diseases of the adrenal, pituitary or thyroid gland, or progression of kidney or liver
 189 disease.

190 7. Interactions with other drugs that lower blood glucose, such as oral antidiabetic agents,
191 salicylates (for example, aspirin), sulfa antibiotics, and certain antidepressants.

192 8. Consumption of alcoholic beverages.

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

- | | | |
|-----|--|-----------------------|
| 194 | • sweating | • drowsiness |
| 195 | • dizziness | • sleep disturbances |
| 196 | • palpitation | • anxiety |
| 197 | • tremor | • blurred vision |
| 198 | • hunger | • slurred speech |
| 199 | • restlessness | • depressed mood |
| 200 | • tingling in the hands, feet, lips, or tongue | • irritability |
| 201 | • lightheadedness | • abnormal behavior |
| 202 | • inability to concentrate | • unsteady movement |
| 203 | • headache | • personality changes |

204 Signs of severe hypoglycemia can include:

- | | | |
|-----|-------------------|------------|
| 205 | • disorientation | • seizures |
| 206 | • unconsciousness | • death |

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

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

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

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

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

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

232 **Hyperglycemia and Diabetic Ketoacidosis (DKA)**

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

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

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

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

245 **Lipodystrophy**

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

250 **Allergy**

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

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

260 **ADDITIONAL INFORMATION**

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

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

265 Another publication, **COUNTDOWN**, is available from the Juvenile Diabetes Research
 266 Foundation International (JDRFI), 120 Wall Street 19th Floor, New York, NY 10005,
 267 1-800-533-CURE (1-800-533-2873).

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

270 Literature revised XXX, 2004

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 272 F-67640 Fegersheim, France
 273 For Eli Lilly and Company
 274 Indianapolis, IN 46285, USA

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276 5.01 PA 9235 FSAMP

Lilly
Disposable Insulin Delivery Device
User Manual

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.

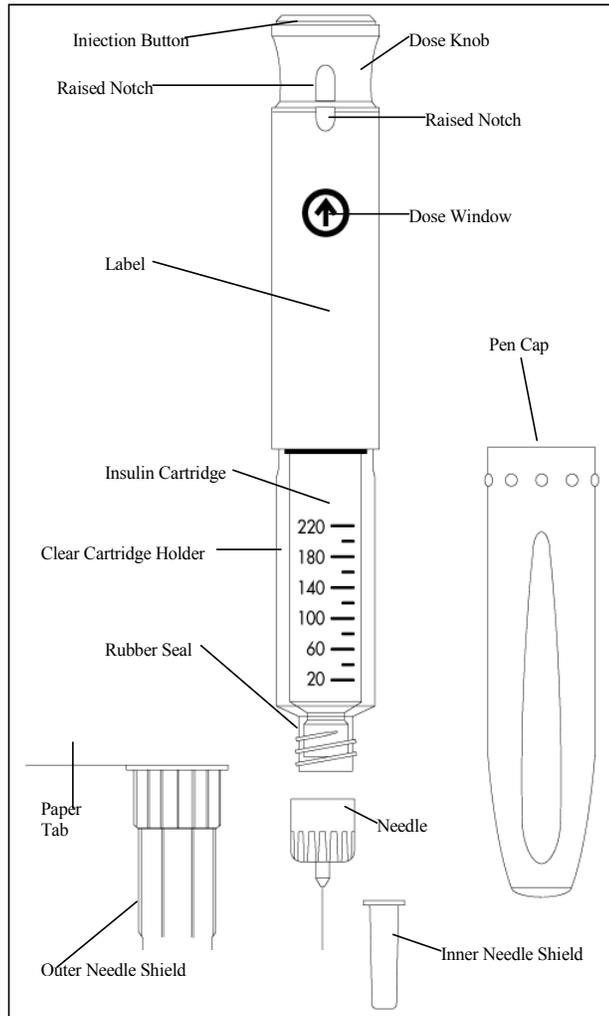
Pen Features

- 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

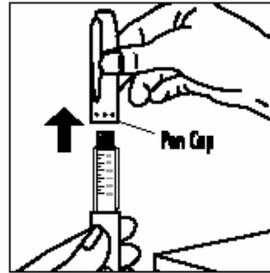
- **Read and follow all of these instructions carefully. If you do not follow these instructions completely, you may get too much or too little insulin.**
- **Use a new needle for each injection.**
 - **Be sure a needle is completely attached to the Pen before priming, setting the dose and injecting 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

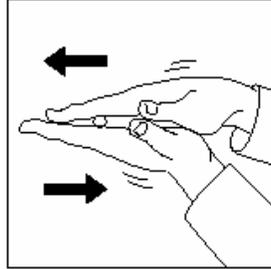
1. Before proceeding, refer to the INFORMATION FOR THE PATIENT insert for instructions on checking the appearance of your insulin.
2. Check the label on the Pen to be sure the Pen contains the type of insulin that has been prescribed for you.
3. Always wash your hands before preparing your Pen for use.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



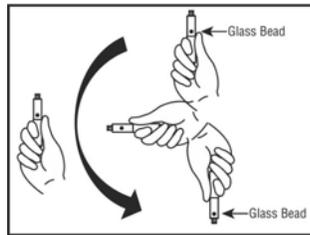
I. Preparing the Pen (Continued)

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

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

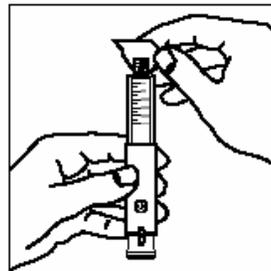


- b. Gently turn the Pen up and down 10 times until the insulin is evenly mixed.



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

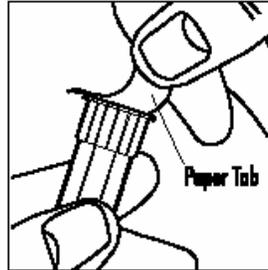
6. Use an alcohol swab to wipe the rubber seal on the end of the Pen.



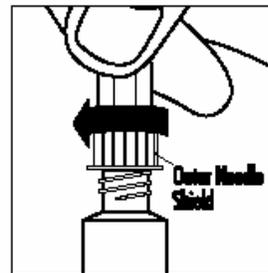
II. Attaching the Needle

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.

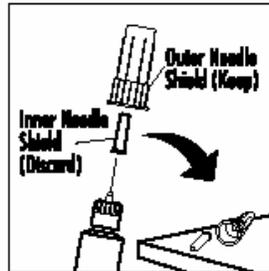


3. Attach the capped needle onto the end of the Pen by turning it clockwise until tight.



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.**

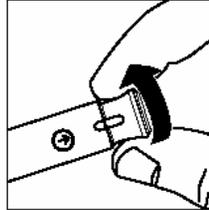


5. Remove the inner needle shield and discard.

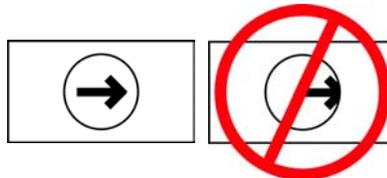
III. Priming the Pen

- **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.



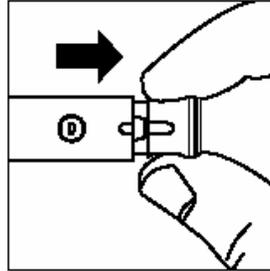
2. If you do not see the arrow in the center of the dose window, push in the injection button fully and turn the dose knob until the arrow is seen in the center of the dose window.



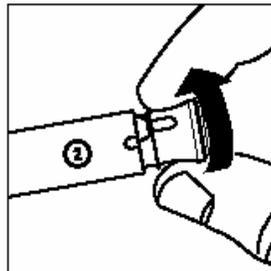
Correct

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.

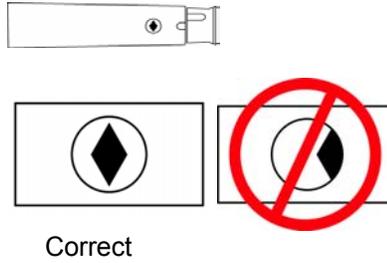
Using your thumb, if possible, push in the injection button completely. Keep pressing and continue to hold the injection button **firmly** while counting **slowly** to 5. You should see either a drop or a stream of insulin come out of the tip of the needle.



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.



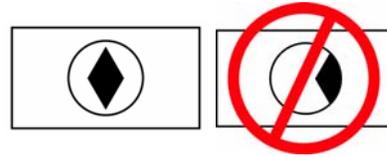
Note: A small air bubble may remain in the cartridge after the completion of the priming step. If you have properly primed the Pen, this small air bubble will not affect your insulin dose.

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

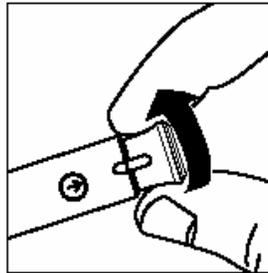
IV. Setting a Dose

- **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.

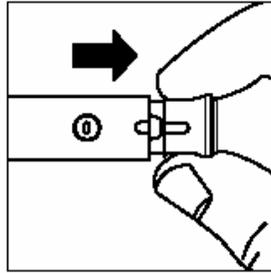


2. Turn the dose knob clockwise until the arrow (→) is seen in the center of the dose window and the notches on the Pen and dose knob are in line.

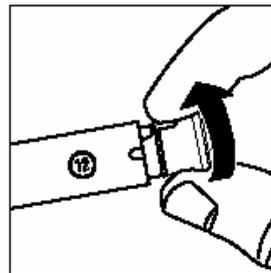


IV. Setting a Dose (Continued)

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.

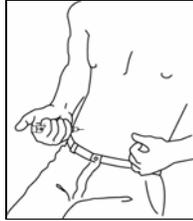
V. Injecting a Dose

- **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.

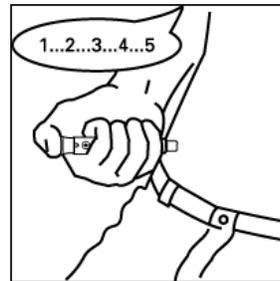
V. Injecting a Dose (Continued)

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.



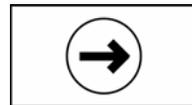
3. Keep pressing and continue to hold the injection button **firmly** while counting **slowly** to 5.



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

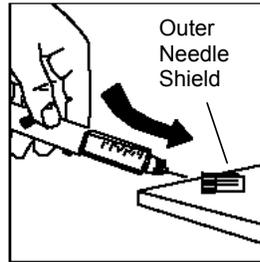


Correct



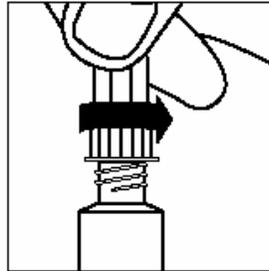
VI. Following an Injection

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.

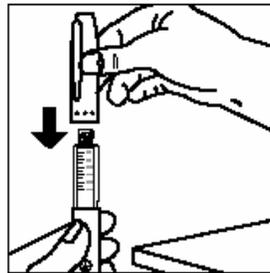


VI. Following an Injection (Continued)

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"> 1) Attach a new needle. 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. 3) Prime the Pen.
2. Insulin does not come out of the needle.	To obtain an accurate dose you must: <ol style="list-style-type: none"> 1) Attach a new needle. 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. 3) Prime the Pen. See Section III. “Priming the Pen”, pages 10-13.

**Questions and Answers
(Continued)**

Problem	Action
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. These numbers should not be used for measuring an insulin dose.

**Questions and Answers
(Continued)**

Problem	Action
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">1) Give the partial dose and then give the remaining dose using a new Pen, or2) Give the full dose with a new Pen.
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)**

Problem	Action
7. Cannot completely push in the injection button when priming the Pen or injecting a dose.	<ol style="list-style-type: none">1) Needle is not attached or is clogged.<ol style="list-style-type: none">a. Attach a new needle.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.c. Prime the Pen.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.

**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

PA 9115 FSAMP

116.5-27.5-186.5

5 x 3 mL
HP8794
100 units per mL

NDC 0002-8794-59

Lilly

Humalog[®] Mix75/25[™] Pen

Rx

75% insulin lispro protamine suspension
25% insulin lispro injection (rDNA origin)

disposable insulin delivery device

Rx only



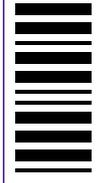
Humalog[®] Mix75/25[™] Pen
75% insulin lispro protamine suspension
25% insulin lispro injection (rDNA origin)

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)

Exp. Date / Control No.



Humalog[®] Mix75/25[™] U-100
5 x 3 mL
100 units per mL
HP8794

75% insulin lispro protamine suspension
25% insulin lispro injection (rDNA origin)
disposable insulin delivery device

Lilly

Manufactured by Lilly France S.A.S.
F-67640 Fegersheim, France
for Eli Lilly and Company
Indianapolis, IN 46285, USA
For information call 1-888-885-4559

Lilly-France
116.5-27.5-186.5
Marbach Pr.-Nr.
97 04 01 31

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

Keep in a cold place. Avoid freezing.
Shake carefully before using. See enclosed insert for proper technique.
**Warning: Any change of insulin should be made cautiously and
only under medical supervision.**
For subcutaneous use only.
See accompanying insert for dosage.

Each mL contains 75 units insulin lispro protamine suspension;
25 units insulin lispro; protamine sulfate, 0.28 mg; glycerin,
1.6 mg; dibasic sodium phosphate, 3.78 mg; m-cresol, 1.76 mg;
zinc oxide content adjusted to provide 0.025 mg zinc ion;
phenol, 0.715 mg; and water for injection.
Hydrochloric acid 10% and/or sodium hydroxide 10% may
have been added to adjust pH.

**IMPORTANT - SEE WARNINGS
ON ACCOMPANYING INSERT**



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

SH 8933 FSAMS

Lilly

Humalog[®] Mix75/25[™]
Pen
75% insulin lispro protamine suspension
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disposable insulin delivery device

U-100
5 x 3 mL
100 units per mL
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