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

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**HUMULIN[®] 70/30 Pen
70% HUMAN INSULIN
ISOPHANE SUSPENSION
AND
30% HUMAN INSULIN INJECTION
(rDNA ORIGIN)
100 Units per mL (U-100)**

11

WARNINGS

12 **THIS LILLY HUMAN INSULIN PRODUCT DIFFERS FROM**
13 **ANIMAL-SOURCE INSULINS BECAUSE IT IS STRUCTURALLY IDENTICAL**
14 **TO THE INSULIN PRODUCED BY YOUR BODY'S PANCREAS AND**
15 **BECAUSE OF ITS UNIQUE MANUFACTURING PROCESS.**

16 **ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUSLY AND ONLY**
17 **UNDER MEDICAL SUPERVISION. CHANGES IN STRENGTH,**
18 **MANUFACTURER, TYPE (E.G., REGULAR, NPH, LENTE, ETC), SPECIES**
19 **(BEEF, PORK, BEEF-PORK, HUMAN), OR METHOD OF MANUFACTURE**
20 **(rDNA VERSUS ANIMAL-SOURCE INSULIN) MAY RESULT IN THE NEED**
21 **FOR A CHANGE IN DOSAGE.**

22 **SOME PATIENTS TAKING HUMULIN[®] (HUMAN INSULIN, rDNA ORIGIN)**
23 **MAY REQUIRE A CHANGE IN DOSAGE FROM THAT USED WITH**
24 **ANIMAL-SOURCE INSULINS. IF AN ADJUSTMENT IS NEEDED, IT MAY**
25 **OCCUR WITH THE FIRST DOSE OR DURING THE FIRST SEVERAL WEEKS**
26 **OR MONTHS.**

27 **TO OBTAIN AN ACCURATE DOSE, CAREFULLY READ AND FOLLOW**
28 **THE "DISPOSABLE INSULIN DELIVERY DEVICE USER MANUAL" AND**
29 **THIS "INFORMATION FOR THE PATIENT" INSERT BEFORE USING THIS**
30 **PRODUCT.**

31 **BEFORE EACH INJECTION, YOU SHOULD PRIME THE PEN, A**
32 **NECESSARY STEP TO MAKE SURE THE PEN IS READY TO DOSE.**
33 **PRIMING THE PEN IS IMPORTANT TO CONFIRM THAT INSULIN COMES**
34 **OUT WHEN YOU PUSH THE INJECTION BUTTON AND TO REMOVE AIR**
35 **THAT MAY COLLECT IN THE INSULIN CARTRIDGE DURING NORMAL**
36 **USE. IF YOU DO NOT PRIME, YOU MAY RECEIVE A WRONG DOSE (*see also***
37 **INSTRUCTIONS FOR PEN USE section).**

38

DIABETES

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

42 To control your diabetes, your doctor has prescribed injections of insulin products to keep your
43 blood glucose at a near-normal level. You have been instructed to test your blood and/or your
44 urine regularly for glucose. Studies have shown that some chronic complications of diabetes
45 such as eye disease, kidney disease, and nerve disease can be significantly reduced if the blood

46 sugar is maintained as close to normal as possible. The American Diabetes Association
 47 recommends that if your pre-meal glucose levels are consistently above 130 mg/dL or your
 48 hemoglobin A_{1c} (HbA_{1c}) is more than 7%, consult your doctor. A change in your diabetes
 49 therapy may be needed. If your blood tests consistently show below-normal glucose levels, you
 50 should also let your doctor know. Proper control of your diabetes requires close and constant
 51 cooperation with your doctor. Despite diabetes, you can lead an active and healthy life if you eat
 52 a balanced diet, exercise regularly, and take your insulin injections as prescribed.

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

70/30 HUMAN INSULIN

Description

57 Humulin is synthesized in a non-disease-producing special laboratory strain of
 58 *Escherichia coli* bacteria that has been genetically altered by the addition of the human gene for
 59 insulin production. Humulin[®] 70/30 is a mixture of 70% Human Insulin Isophane Suspension
 60 and 30% Human Insulin Injection, (rDNA origin). It is an intermediate-acting insulin combined
 61 with the more rapid onset of action of regular insulin. The duration of activity may last up to
 62 24 hours following injection. The time course of action of any insulin may vary considerably in
 63 different individuals or at different times in the same individual. As with all insulin preparations,
 64 the duration of action of Humulin 70/30 is dependent on dose, site of injection, blood supply,
 65 temperature, and physical activity. Humulin 70/30 is a sterile suspension and is for subcutaneous
 66 injection only. It should not be used intravenously or intramuscularly. The concentration of
 67 Humulin 70/30 in the Humulin 70/30 Pen is 100 units/mL (U-100).

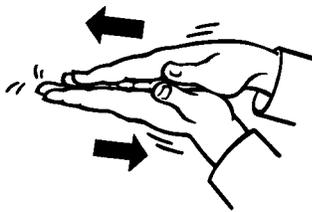
Identification

70 Humulin disposable insulin delivery devices, by Eli Lilly and Company, are available in
 71 2 formulations — NPH and 70/30.

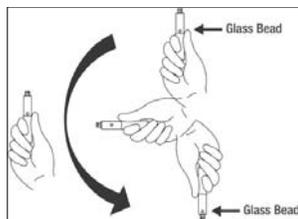
72 Your doctor has prescribed the type of insulin that he/she believes is best for you. **DO NOT**
 73 **USE ANY OTHER INSULIN EXCEPT ON HIS/HER ADVICE AND DIRECTION.**

74 The Humulin 70/30 Pen is available in boxes of 5 disposable insulin delivery devices (“insulin
 75 Pens”). The Humulin 70/30 Pen is not designed to allow any other insulin to be mixed in its
 76 cartridge, or for the cartridge to be removed.

77 Always examine the appearance of Humulin 70/30 suspension in the insulin Pen before
 78 administering a dose. A cartridge of Humulin 70/30 contains a small glass bead to assist in
 79 mixing. Humulin 70/30 Pen must be rolled between the palms 10 times and inverted 180°
 80 10 times before each injection so that the contents are uniformly mixed (*see* Figures 1 and 2).
 81 Inspect the Humulin 70/30 suspension for uniform mixing and repeat the above steps as
 82 necessary.



83 Figure 1.



84 Figure 2.

85 Humulin 70/30 should look uniformly cloudy or milky after mixing. Do not use if the insulin
 86 substance (the white material) remains visibly separated from the liquid after mixing. Do not use
 87 the Humulin 70/30 Pen if there are clumps in the insulin after mixing. Do not use the
 88 Humulin 70/30 Pen if solid white particles stick to the walls of the cartridge, giving it a frosted
 appearance.

89 Always check the appearance of the Humulin 70/30 suspension in the insulin Pen before using,
 90 and if you note anything unusual in the appearance of Humulin 70/30 suspension or notice your
 91 insulin requirements changing markedly, consult your doctor.

92 Never attempt to remove the cartridge from the Humulin 70/30 Pen. Inspect the cartridge
 93 through the clear cartridge holder.

94 **Storage**

95 Humulin 70/30 Pens **that have not been used** should be stored in a refrigerator but not in the
 96 freezer. The Humulin 70/30 Pen that you are currently using should not be refrigerated but
 97 should be kept as cool as possible (below 86°F [30°C]) and away from heat and light. Do not use
 98 an insulin Pen if it has been frozen. Unrefrigerated Humulin 70/30 Pens **must be discarded**
 99 **after 10 days**, even if they still contain insulin. Do not use Humulin 70/30 Pens after the
 100 expiration date stamped on the label.

101 **INSTRUCTIONS FOR PEN USE**

102 It is important to read, understand, and follow the instructions in the “Disposable Insulin
 103 Delivery Device User Manual” before using. Failure to follow instructions may result in a wrong
 104 insulin dose. The Pen must be primed before each injection to make sure the Pen is ready to
 105 dose. Performing the priming step is important to confirm that insulin comes out when you push
 106 the injection button, and to remove air that may collect in the insulin cartridge during normal
 107 use.

108 NEVER SHARE INSULIN PENS, CARTRIDGES, OR NEEDLES.

109 **PREPARING THE PEN FOR INJECTION**

- 110 1. Always check the appearance of the Humulin 70/30 suspension in the insulin Pen before
 111 using.
- 112 2. Roll the Humulin 70/30 Pen between the palms 10 times (*see* Figure 1 above).
- 113 3. Holding the Humulin 70/30 Pen by one end, invert it 180° slowly 10 times to allow the
 114 glass bead to travel the full length of the cartridge with each inversion (*see* Figure 2
 115 above). The cartridge is contained in the clear cartridge holder of the Humulin 70/30 Pen.
- 116 4. Inspect the appearance of the Humulin 70/30 suspension to make sure the contents look
 117 uniformly cloudy or milky. If not, repeat the above steps until the contents are mixed. Do
 118 not use a Humulin 70/30 Pen if there are clumps in the insulin or if solid white particles
 119 stick to the walls of the cartridge.
- 120 5. Follow the instructions in the “Disposable Insulin Delivery Device User Manual” for
 121 these steps:
 - 122 • Preparing the Pen
 - 123 • Attaching the Needle
 - 124 • Priming the Pen. **The Pen must be primed before each injection to make sure the Pen is**
 125 **ready to dose.** Performing the priming step is important to confirm that insulin comes out
 126 when you push the injection button, and to remove air that may collect in the insulin
 127 cartridge during normal use.
 - 128 • Setting a Dose
 - 129 • Injecting a Dose
 - 130 • Following an Injection

131 **PREPARING FOR INJECTION**

- 132 1. Wash your hands.
- 133 2. To avoid tissue damage, choose a site for each injection that is at least 1/2 inch from the
 134 previous injection site. The usual sites of injection are abdomen, thighs, and arms.
- 135 3. Cleanse the skin with alcohol where the injection is to be made.
- 136 4. With one hand, stabilize the skin by spreading it or pinching up a large area.
- 137 5. Inject the dose as instructed by your doctor.
- 138 6. After dispensing a dose, pull the needle out and apply gentle pressure over the injection
 139 site for several seconds. Do not rub the area.

- 140 7. Immediately after an injection, remove the needle from the Humulin 70/30 Pen. Doing so
 141 will guard against contamination, leakage, reentry of air, and needle clogs. **Do not reuse**
 142 **needles.** Place the used needle in a puncture-resistant disposable container and properly
 143 dispose of it as directed by your Health Care Professional.

144 **DOSAGE**

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

148 Your usual insulin dose may be affected by changes in your food, activity, or work schedule.
 149 Carefully follow your doctor's instructions to allow for these changes. Other things that may
 150 affect your insulin dose are:

151 **Illness**

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

156 **Pregnancy**

157 Good control of diabetes is especially important for you and your unborn baby. Pregnancy may
 158 make managing your diabetes more difficult. If you are planning to have a baby, are pregnant, or
 159 are nursing a baby, consult your doctor.

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 hypoglycemic activity, such as oral
 164 hypoglycemics, salicylates (for example, aspirin), sulfa antibiotics, and certain antidepressants.
 165 Always discuss any medications you are taking with your doctor.

166 **Exercise**

167 Exercise may lower your body's need for insulin during and for some time after the activity.
 168 Exercise may also speed up the effect of an insulin dose, especially if the exercise involves the
 169 area of injection site (for example, the leg should not be used for injection just prior to running).
 170 Discuss with your doctor how you should adjust your regimen to accommodate exercise.

171 **Travel**

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

174 **COMMON PROBLEMS OF DIABETES**

175 **Hypoglycemia (Insulin Reaction)**

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

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

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

- | | | |
|-----|--|-----------------------|
| 189 | • sweating | • drowsiness |
| 190 | • dizziness | • sleep disturbances |
| 191 | • palpitation | • anxiety |
| 192 | • tremor | • blurred vision |
| 193 | • hunger | • slurred speech |
| 194 | • restlessness | • depressed mood |
| 195 | • tingling in the hands, feet, lips, or tongue | • irritability |
| 196 | • lightheadedness | • abnormal behavior |
| 197 | • inability to concentrate | • unsteady movement |
| 198 | • headache | • personality changes |

199 Signs of severe hypoglycemia can include:

- | | | |
|-----|-------------------|------------|
| 200 | • disorientation | • seizures |
| 201 | • unconsciousness | • death |

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

203 Early warning symptoms of hypoglycemia may be different or less pronounced under certain
204 conditions, such as long duration of diabetes, diabetic nerve disease, medications such as
205 beta-blockers, change in insulin preparations, or intensified control (3 or more insulin injections
206 per day) of diabetes.

207 **A few patients who have experienced hypoglycemic reactions after transfer from**
208 **animal-source insulin to human insulin have reported that the early warning symptoms of**
209 **hypoglycemia were less pronounced or different from those experienced with their**
210 **previous insulin.**

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

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

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

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

228 **Hyperglycemia and Diabetic Acidosis**

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

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

234 In patients with insulin-dependent diabetes, prolonged hyperglycemia can result in diabetic
235 acidosis. The first symptoms of diabetic acidosis usually come on gradually, over a period of
236 hours or days, and include a drowsy feeling, flushed face, thirst, loss of appetite, and fruity odor
237 on the breath. With acidosis, urine tests show large amounts of glucose and acetone. Heavy
238 breathing and a rapid pulse are more severe symptoms. If uncorrected, prolonged hyperglycemia

239 or diabetic acidosis can lead to nausea, vomiting, dehydration, loss of consciousness or death.
 240 Therefore, it is important that you obtain medical assistance immediately.

241 **Lipodystrophy**

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

246 **Allergy to Insulin**

247 *Local Allergy* — Patients occasionally experience redness, swelling, and itching at the site of
 248 injection of insulin. This condition, called local allergy, usually clears up in a few days to a few
 249 weeks. In some instances, this condition may be related to factors other than insulin, such as
 250 irritants in the skin cleansing agent or poor injection technique. If you have local reactions,
 251 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 to insulin, 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 Humulin and Humulin 70/30 Pens can be obtained by calling
 266 The 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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273 5.0 PA 9143-A FSAMP

Lilly
Disposable Insulin Delivery Device
User Manual

Instructions for Use

Read and follow these step by step instructions carefully. Failure to follow these instructions completely, including the priming step, may result in a wrong insulin dose. Also, read the ***INFORMATION FOR THE PATIENT*** insert enclosed in your Pen box.

Pen Features

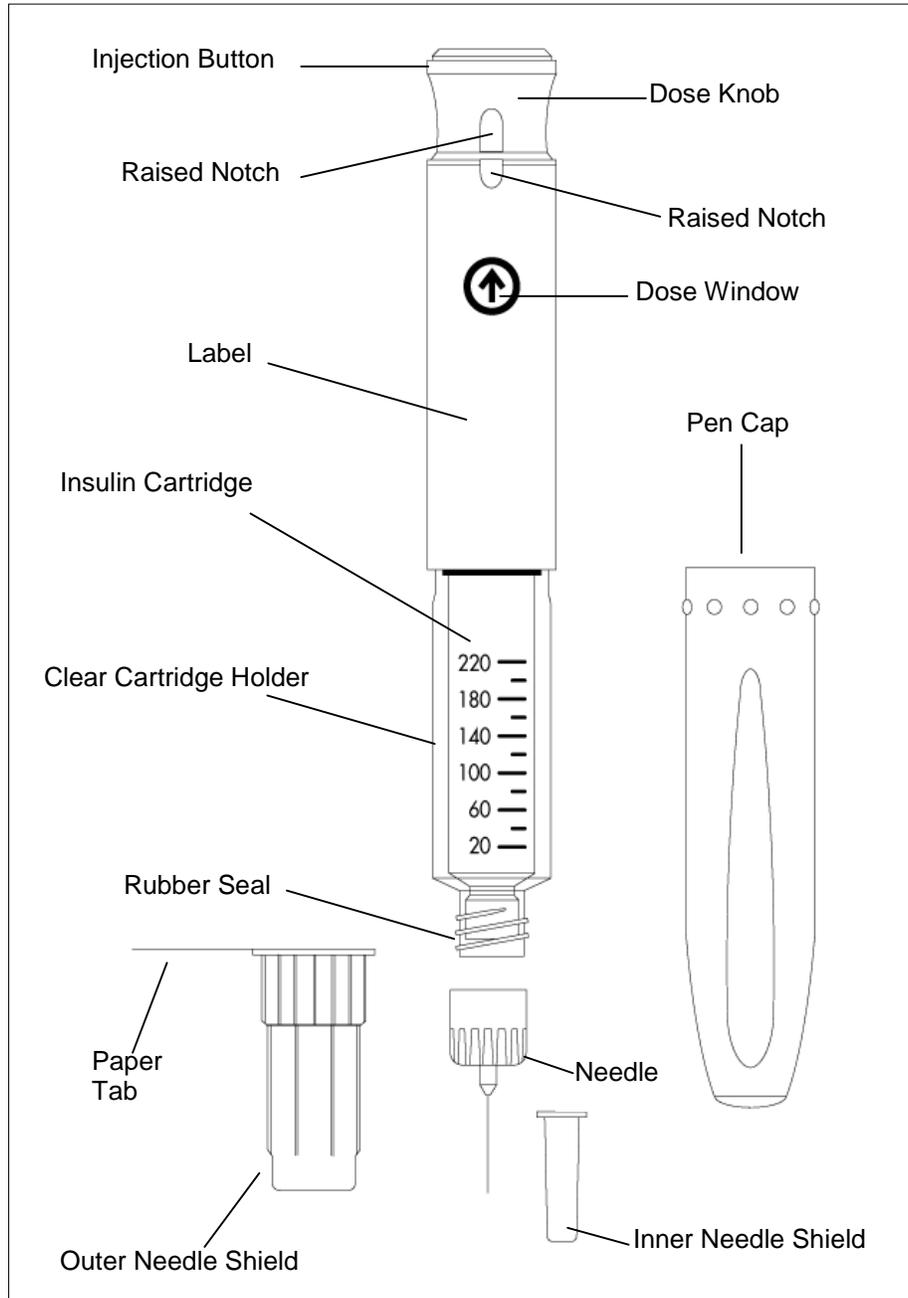
- A multiple dose, disposable insulin delivery device (“insulin Pen”) containing 3 mL (300 units) of U-100 insulin
- Delivers up to 60 units per dose
- Doses can be dialed by single units



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Pen Parts



Important Notes

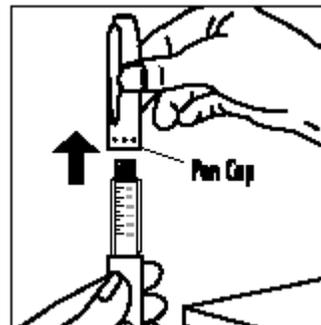
- **Please read these instructions carefully before using your Pen. Failure to follow these instructions completely, including the priming step, may result in a wrong dose.**
- Use a new needle for each injection.
- Be sure a needle is attached to the Pen before priming, setting (dialing) the dose and injecting your insulin.
- **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 receive a wrong dose.**
- 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.

Important Notes (Continued)

- Keep your Pen out of the reach of children.
- Pens not being used should be stored in a refrigerator but not in a freezer. Refer to the *INFORMATION FOR THE PATIENT* insert for complete storage instructions.
- 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.
- **Any changes in insulin should be made cautiously and only under medical supervision.**

I. Preparing the Pen

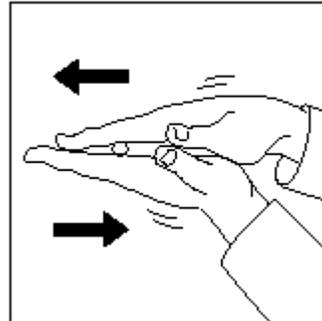
1. Before proceeding, refer to the *INFORMATION FOR THE PATIENT* insert for instructions on checking the appearance of your insulin.
2. Check the label on the Pen to be sure the Pen contains the type of insulin that has been prescribed for you.
3. Always wash your hands before preparing your Pen for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



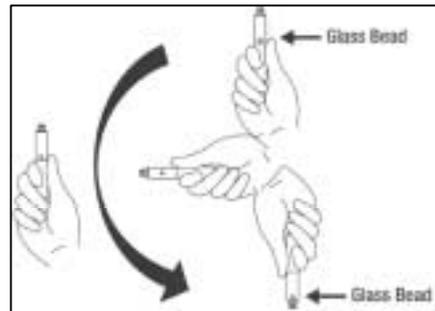
I. Preparing the Pen (Continued)

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

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

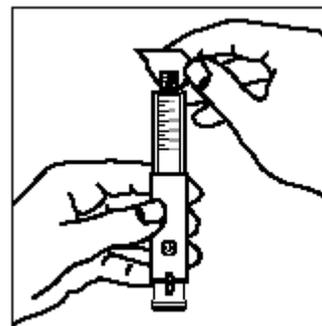


b. Gently turn the Pen up and down 10 times until the insulin is evenly mixed.



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.

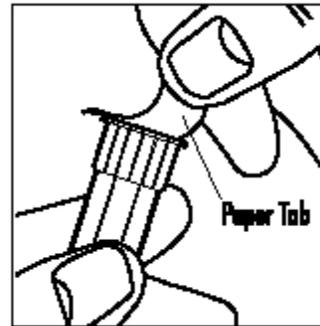


II. Attaching the Needle

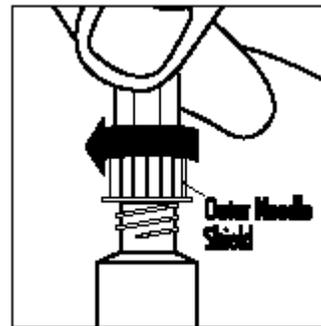
This device is suitable for use with Becton Dickinson and Company's insulin pen needles.

1. Always use a new needle for each injection. 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.

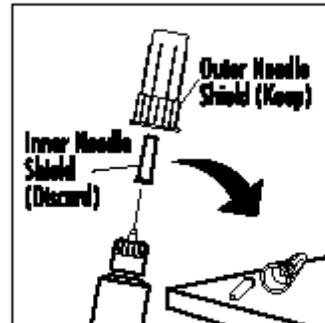


3. Attach the capped needle onto the end of the Pen by turning it clockwise until tight.



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.**

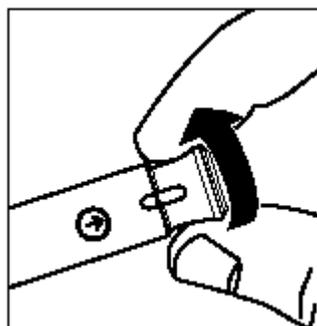


5. Remove the inner needle shield and discard.

III. Priming the Pen

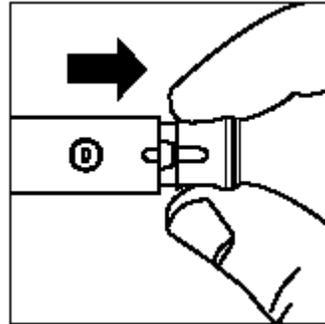
- **Always use a new needle for each injection.**
- **The Pen must be primed before each injection to make sure the Pen is ready to dose.** Performing the priming step is important to confirm that insulin comes out when you push the injection button, and to remove air that may collect in the insulin cartridge during normal use.
- **If you do not prime, you may receive a wrong dose.**

1. You cannot prime your Pen until you can see the arrow (→) in the dose window. If a number or a blank space is in the dose window, push in the injection button completely until a diamond (◆) or arrow (→) is seen. When diamonds (◆) can be seen in the dose window, turn the dose knob clockwise until the arrow (→) is seen and the notches on the Pen and dose knob are in line.

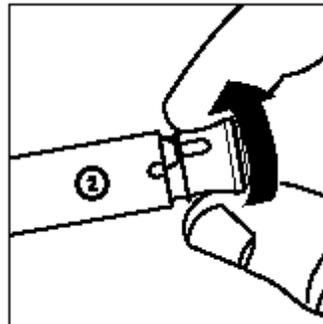


III. Priming the Pen (Continued)

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

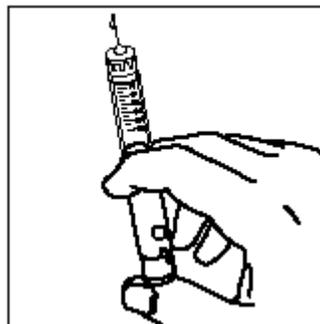


3. Turn the dose knob clockwise until the number "2" is seen in the dose window. If the number you have dialed is too high, simply turn the dose knob backward until the number 2 is seen in the dose window.



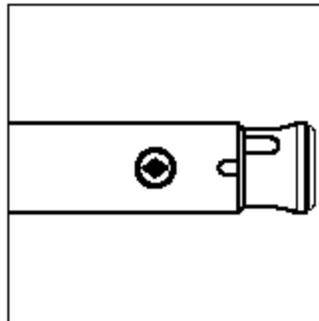
III. Priming the Pen (Continued)

4. 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 and maintain pressure until the insulin flow stops. 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 4. If after several attempts insulin does not come out of the tip of the needle, refer to the "Questions and Answers" section at the end of this manual.



III. Priming the Pen (Continued)

5. At the completion of the priming step, a diamond (◆) must be seen in the dose window.

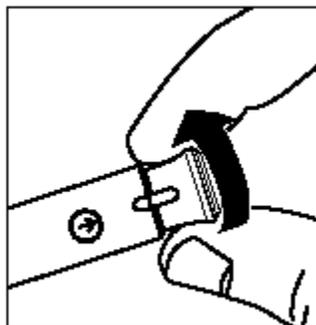


Note: A small air bubble may remain in the cartridge after the completion of the priming step. If you have properly primed the Pen, this small air bubble will not affect your insulin dose.

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

IV. Setting a Dose

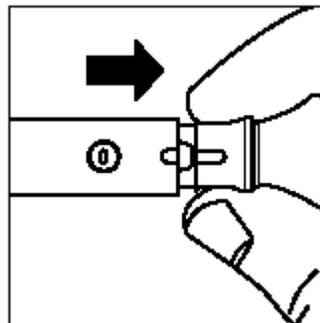
- **Always use a new needle for each injection. Storing the Pen with the needle attached may allow insulin to leak from the Pen and air bubbles to form in the cartridge.**
 - **Caution: Do not push in the injection button while setting your dose. Failure to follow these instructions carefully may result in an inaccurate insulin dose.***
1. Pen has been primed and a diamond (◆) can be seen in the dose window.
 2. Turn the dose knob clockwise until the arrow (→) is seen in the dose window and the notches on the Pen and dose knob are in line.



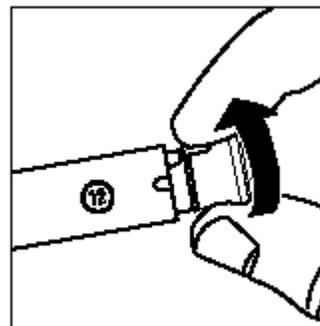
*See Page 16.

IV. Setting a Dose (Continued)

3. With the arrow (→) in 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.



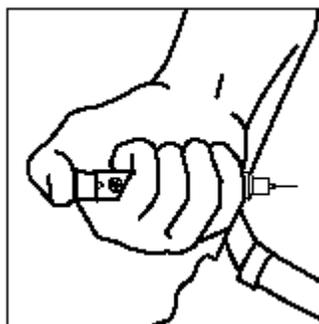
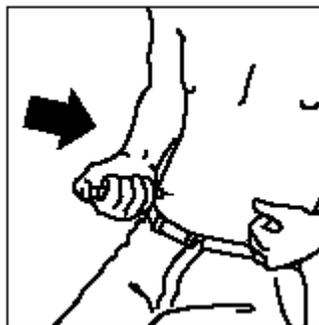
5. If you cannot dial a full dose, see the “Questions and Answers” section at the end of this manual.

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 an inaccurate insulin dose.***
 - **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 at the end of this manual.**
- * If you have set (dialed) a dose and pushed in the injection button without the needle attached or if no insulin comes out of the needle, see the “Questions and Answers” section.

V. Injecting a Dose (Continued)

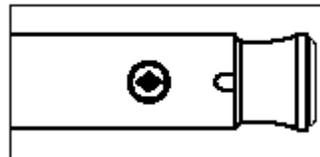
1. Wash hands. Prepare the skin and use the injection technique recommended by your Health Care Professional.
2. Inject the insulin by using your thumb, if possible, to completely push in the injection button. When the injection button has been completely pushed in (**a diamond (♦) or arrow (→) must be seen in the dose window to indicate that the injection button has been completely pushed in**), continue to hold it down and count **slowly** to 5. After dispensing a dose, pull the needle out and apply gentle pressure over the injection site for several seconds. Do not rub the area.



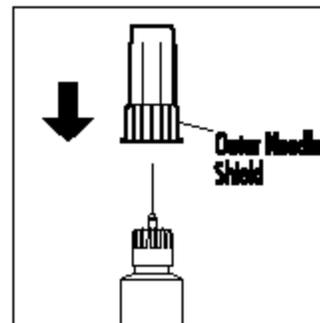
VI. Following an Injection

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.

1. Check that the injection button has been completely pushed in and you can see a diamond (◆) or arrow (→) in the dose window. If a diamond (◆) or arrow (→) cannot be seen in the dose window, your full dose has not been delivered. Contact your Health Care Professional immediately for additional instructions.

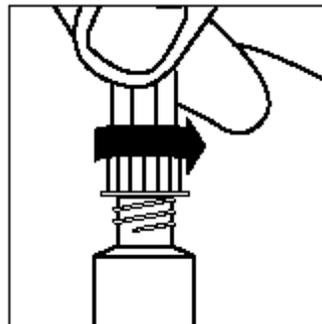


2. Carefully replace the **outer needle shield**.

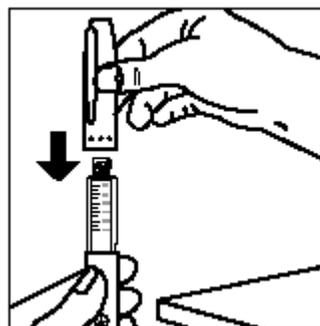


VI. Following an Injection (Continued)

3. Remove the capped needle by turning it counterclockwise. Place the used needle in a puncture-resistant disposable container and properly dispose of it 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.

Questions and Answers

| Problem | Action |
|---|---|
| Dose dialed and injection button pushed in without a needle attached. | To obtain an accurate dose you must: 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 dose window. 3) Prime the Pen. |
| Insulin does not come out of the needle. | To obtain an accurate dose you must: 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 dose window. 3) Prime the Pen. |

**Questions and Answers
(Continued)**

| Problem | Action |
|---|---|
| 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. |
| 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 |
|---|--|
| 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. |
| 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)**

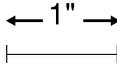
| Problem | Action |
|--|---|
| Cannot completely push in the injection button when priming the Pen or injecting a dose. | <ol style="list-style-type: none">1) Needle is not attached or is clogged.<ol style="list-style-type: none">a. Attach a new needle.b. Push in the injection button completely (even if a "0" is seen in the window) until a diamond (◆) or arrow (→) is seen in the 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-LillyRx (1-800-545-5979)**

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

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116-5-27-5-186,5

3 mL *Lilly* 5 x 3 mL disposable insulin delivery devices
Humulin[®] 70/30 Pen
70% human insulin isophane suspension
30% human insulin injection
(rDNA origin)

Lilly **5 x 3 mL disposable insulin delivery devices**
NDC 0002-8770-59
HP 8770
100 Units per mL

Humulin[®] 70/30 Pen

70% human insulin isophane suspension
30% human insulin injection
(rDNA origin)
disposable insulin delivery device



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

HP 8770
U-100
disposable insulin delivery device
For information call 1-800-545-5979

Exp. Date / Control No.



3 mL *Lilly* 5 x 3 mL disposable insulin delivery devices
Humulin[®] 70/30 Pen
70% human insulin isophane suspension
30% human insulin injection
(rDNA origin)



HP 8770
disposable insulin delivery device

Lilly-France
116-5-27-5-186,5
Matabach P.-Nr.
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. See enclosed insert.

For subcutaneous use.

As with any drug, if you are pregnant or nursing a baby, seek professional advice when using this product.

Shake Carefully Before Using.

See Enclosed Insert for Proper Technique.

Each mL contains 70 units human insulin isophane (70% human insulin isophane injection) and 30 units human insulin injection (30% human insulin injection). 10% and 100% added during manufacture as preservatives.

Lilly
Manufactured by Lilly France S.A.S.
F-97540 Fegersheim, France
for Eli Lilly and Company
Indianapolis, IN 46285, USA
1-800-545-5979

IMPORTANT - SEE WARNINGS ON ENCLOSED INSERT



3 0002-8770-59 7

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

SH MAQ 002 AM

3 mL *Lilly* 5 x 3 mL disposable insulin delivery devices
Humulin[®] 70/30 Pen
70% human insulin isophane suspension
30% human insulin injection
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HP 8770
disposable insulin delivery device