

1
2 **INFORMATION FOR THE PATIENT**
3 **3 ML DISPOSABLE INSULIN DELIVERY DEVICE**

4 **HUMULIN[®] N Pen**
5 **NPH**
6 **HUMAN INSULIN**
7 **(rDNA ORIGIN) ISOPHANE SUSPENSION**
8 **100 UNITS PER ML (U-100)**

9 **WARNINGS**

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

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

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

25 **TO OBTAIN AN ACCURATE DOSE, CAREFULLY READ AND FOLLOW**
26 **THE “DISPOSABLE INSULIN DELIVERY DEVICE USER MANUAL” AND**
27 **THIS INFORMATION FOR THE PATIENT INSERT BEFORE USING THIS**
28 **PRODUCT. BEFORE EACH INJECTION, YOU SHOULD PRIME THE PEN, A**
29 **NECESSARY STEP TO MAKE SURE THE PEN IS READY TO DOSE.**
30 **PRIMING THE PEN IS IMPORTANT TO CONFIRM THAT INSULIN COMES**
31 **OUT WHEN YOU PUSH THE INJECTION BUTTON AND TO REMOVE AIR**
32 **THAT MAY COLLECT IN THE INSULIN CARTRIDGE DURING NORMAL**
33 **USE. IF YOU DO NOT PRIME, YOU MAY RECEIVE A WRONG DOSE (*see also***
34 **INSTRUCTIONS FOR PEN USE section).**

35 **DIABETES**

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

39 To control your diabetes, your doctor has prescribed injections of insulin products to keep your
40 blood glucose at a near-normal level. You have been instructed to test your blood and/or your
41 urine regularly for glucose. Studies have shown that some chronic complications of diabetes
42 such as eye disease, kidney disease, and nerve disease can be significantly reduced if the blood
43 sugar is maintained as close to normal as possible. The American Diabetes Association
44 recommends that if your premeal glucose levels are consistently above 130 mg/dL or your
45 hemoglobin A_{1c} (HbA_{1c}) is more than 7%, consult your doctor. A change in your diabetes

46 therapy may be needed. If your blood tests consistently show below-normal glucose levels, you
 47 should also let your doctor know. Proper control of your diabetes requires close and constant
 48 cooperation with your doctor. Despite diabetes, you can lead an active and healthy life if you eat
 49 a balanced diet, exercise regularly, and take your insulin injections as prescribed.

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

53

NPH HUMAN INSULIN

Description

55 Humulin is synthesized in a non-disease-producing special laboratory strain of *Escherichia*
 56 *coli* bacteria that has been genetically altered by the addition of the human gene for insulin
 57 production. Humulin[®] N ([human insulin \[rDNA origin\] isophane suspension](#)) is a crystalline
 58 suspension of human insulin with protamine and zinc providing an intermediate-acting insulin
 59 with a slower onset of action and a longer duration of activity (up to 24 hours) than that of
 60 regular insulin. The time course of action of any insulin may vary considerably in different
 61 individuals or at different times in the same individual. As with all insulin preparations, the
 62 duration of action of Humulin N is dependent on dose, site of injection, blood supply,
 63 temperature, and physical activity. Humulin N is a sterile suspension and is for subcutaneous
 64 injection only. It should not be used intravenously or intramuscularly. The concentration of
 65 Humulin N in Humulin N Pen is 100 units/mL (U-100).

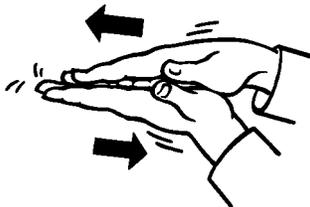
Identification

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

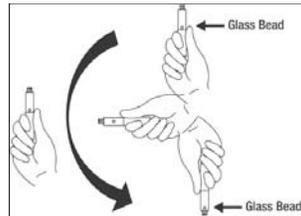
68 Your doctor has prescribed the type of insulin that he/she believes is best for you. **DO NOT**
 69 **USE ANY OTHER INSULIN EXCEPT ON HIS/HER ADVICE AND DIRECTION.**

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

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



79 Figure 1.



80 Figure 2.

81

82

81 Humulin N should look uniformly cloudy or milky after mixing. Do not use if the insulin
 82 substance (the white material) remains visibly separated from the liquid after mixing. Do not use
 83 the Humulin N Pen if there are clumps in the insulin after mixing. Do not use the Humulin N Pen
 84 if solid white particles stick to the walls of the cartridge, giving it a frosted appearance.

85 Always check the appearance of the Humulin N suspension in the insulin Pen before using,
 86 and if you note anything unusual in the appearance of Humulin N suspension or notice your
 87 insulin requirements changing markedly, consult your doctor.
 88 Never attempt to remove the cartridge from the Humulin N Pen. Inspect the cartridge through
 89 the clear cartridge holder.

90 **Storage**

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

93 **In-use:** Humulin N Pens in-use should **NOT** be refrigerated but should be kept at room
 94 temperature (below 86°F [30°C]) away from direct heat and light. Humulin N Pens in-use must
 95 be discarded **after 2 weeks**, even if they still contain Humulin N.

96 Do not use Humulin N Pens after the expiration date stamped on the label.

97 **INSTRUCTIONS FOR PEN USE**

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

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

105 **PREPARING THE INSULIN PEN FOR INJECTION**

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

127 **PREPARING FOR INJECTION**

- 128 1. Wash your hands.
- 129 2. To avoid tissue damage, choose a site for each injection that is at least 1/2 inch from the
 130 previous injection site. The usual sites of injection are abdomen, thighs, and arms.
- 131 3. Cleanse the skin with alcohol where the injection is to be made.
- 132 4. With one hand, stabilize the skin by spreading it or pinching up a large area.
- 133 5. Inject the dose as instructed by your doctor.

- 134 6. After dispensing a dose, pull the needle out and apply gentle pressure over the injection
 135 site for several seconds. Do not rub the area.
- 136 7. Immediately after an injection, remove the needle from the Humulin N Pen. Doing so will
 137 guard against contamination, leakage, reentry of air, and needle clogs. **Do not reuse**
 138 **needles.** Place the used needle in a puncture-resistant disposable container and properly
 139 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 case of diabetes is different, this schedule has been individualized for you.

143 Your usual insulin dose 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 insulin dose 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.

155 **Medication**

156 Insulin requirements may be increased if you are taking other drugs with hyperglycemic
 157 activity, such as oral contraceptives, corticosteroids, or thyroid replacement therapy. Insulin
 158 requirements may be reduced in the presence of drugs with hypoglycemic activity, such as oral
 159 hypoglycemics, salicylates (for example, aspirin), sulfa antibiotics, and certain antidepressants.
 160 Always discuss any medications you are taking with your doctor.

161 **Exercise**

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

166 **Travel**

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

169 **COMMON PROBLEMS OF DIABETES**

170 **Hypoglycemia (Insulin Reaction)**

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

- 173 1. Taking too much insulin
- 174 2. Missing or delaying meals
- 175 3. Exercising or working more than usual
- 176 4. An infection or illness (especially with diarrhea or vomiting)
- 177 5. A change in the body's need for insulin
- 178 6. Diseases of the adrenal, pituitary or thyroid gland, or progression of kidney or liver
 179 disease

180 7. Interactions with other drugs that lower blood glucose, such as oral hypoglycemics,
181 salicylates (for example, aspirin), sulfa antibiotics, and certain antidepressants

182 8. Consumption of alcoholic beverages

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

- | | | |
|-----|--|-----------------------|
| 184 | • sweating | • drowsiness |
| 185 | • dizziness | • sleep disturbances |
| 186 | • palpitation | • anxiety |
| 187 | • tremor | • blurred vision |
| 188 | • hunger | • slurred speech |
| 189 | • restlessness | • depressed mood |
| 190 | • tingling in the hands, feet, lips, or tongue | • irritability |
| 191 | • lightheadedness | • abnormal behavior |
| 192 | • inability to concentrate | • unsteady movement |
| 193 | • headache | • personality changes |

194 Signs of severe hypoglycemia can include:

- | | | |
|-----|-------------------|------------|
| 195 | • disorientation | • seizures |
| 196 | • unconsciousness | • death |

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

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

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

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

212 Mild to moderate hypoglycemia may be treated by eating foods or drinks that contain sugar.

213 Patients should always carry a quick source of sugar, such as candy mints or glucose tablets.

214 More severe hypoglycemia may require the assistance of another person. Patients who are unable
215 to take sugar orally or who are unconscious require an injection of glucagon or should be treated
216 with intravenous administration of glucose at a medical facility.

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

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

223 **Hyperglycemia and Diabetic Acidosis**

224 Hyperglycemia (too much glucose in the blood) may develop if your body has too little insulin.

225 Hyperglycemia can be brought about by:

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

229 In patients with insulin-dependent diabetes, prolonged hyperglycemia can result in diabetic
 230 acidosis. The first symptoms of diabetic acidosis usually come on gradually, over a period of
 231 hours or days, and include a drowsy feeling, flushed face, thirst, loss of appetite, and fruity odor
 232 on the breath. With acidosis, urine tests show large amounts of glucose and acetone. Heavy
 233 breathing and a rapid pulse are more severe symptoms. If uncorrected, prolonged hyperglycemia
 234 or diabetic acidosis can lead to nausea, vomiting, dehydration, loss of consciousness or death.
 235 Therefore, it is important that you obtain medical assistance immediately.

236 **Lipodystrophy**

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

241 **Allergy to Insulin**

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

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

252 **ADDITIONAL INFORMATION**

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

254 **DIABETES FORECAST** is a national magazine designed especially for patients with
 255 diabetes and their families and is available on subscription from the American Diabetes
 256 Association, National Service Center, 1660 Duke Street, Alexandria, Virginia 22314,
 257 1-800-DIABETES (1-800-342-2383).

258 Another publication, **DIABETES COUNTDOWN**, is available from the Juvenile Diabetes
 259 Foundation, 120 Wall Street 19th Floor, New York, New York 10005-4001, 1-800-JDF-CURE
 260 (1-800-533-2873).

261 Additional information about Humulin and Humulin N Pen can be obtained by calling
 262 1-888-88-LILLY (1-888-885-4559).

263 Literature issued XXX 2003

264 **Eli Lilly and Company, Indianapolis, IN 46285, USA**

265

266 A3.0 NL 3680 AMP

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267

268

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A3.0 NL 3730 AMP

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

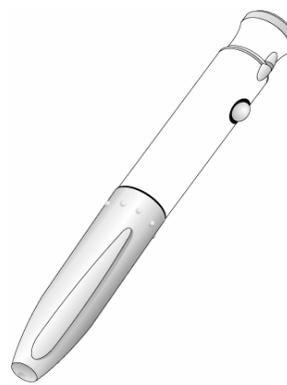
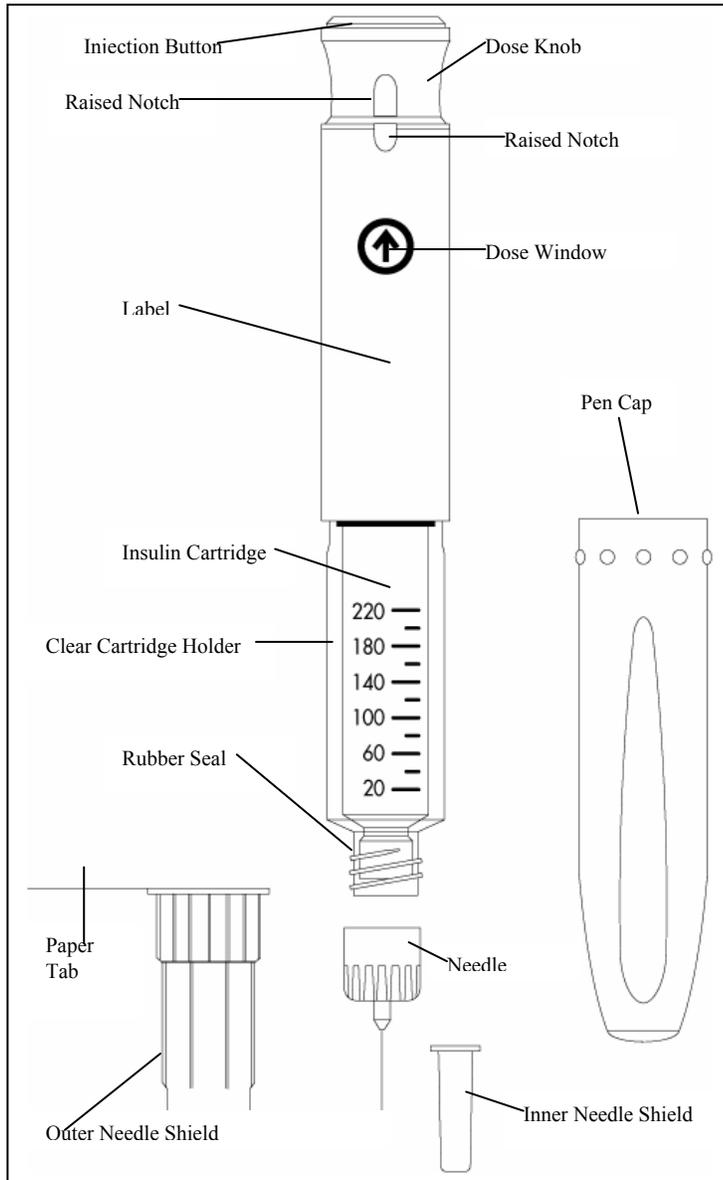


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Pen Parts



Important Notes

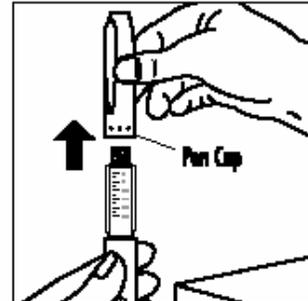
- **Please read these instructions carefully before using your Pen. Failure to follow these instructions completely, including the priming step, may result in a wrong dose.**
- Use a new needle for each injection.
- Be sure a needle is attached to the Pen before priming, setting (dialing) the dose and 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 that have not been used 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.
- 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.
- **Any changes in insulin should be made cautiously and only under medical supervision.**

I. Preparing the Pen

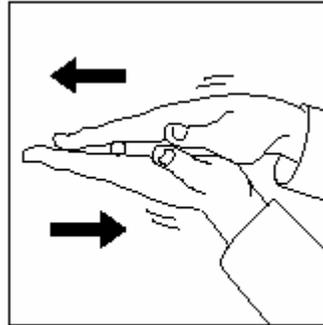
1. Before proceeding, refer to the *Information for the Patient* insert for instructions on checking the appearance of your insulin.
2. Check the label on the Pen to be sure the Pen contains the type of insulin that has been prescribed for you.
3. Always wash your hands before preparing your Pen for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



I. Preparing the Pen (Continued)

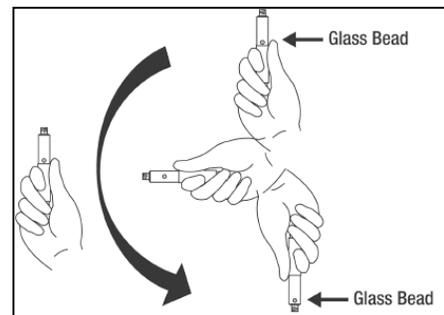
5. If your insulin is a suspension (cloudy):

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

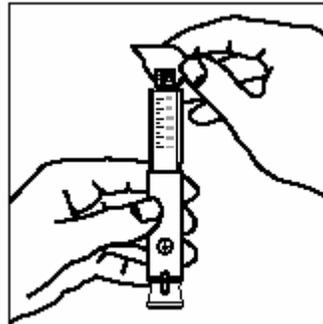


- b. Gently turn the Pen up and down 10 times until the insulin is evenly mixed.

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



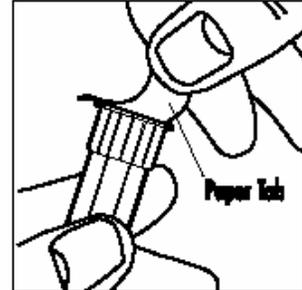
6. Use an alcohol swab to wipe the rubber seal on the end of the Pen.



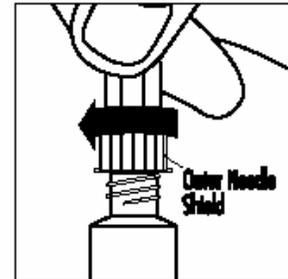
II. Attaching the Needle

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.

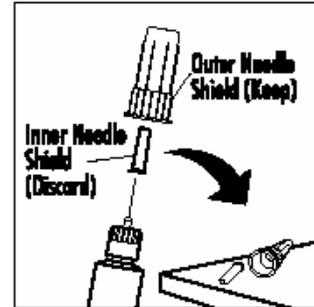


3. Attach the capped needle onto the end of the Pen by turning it clockwise until tight.



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.**

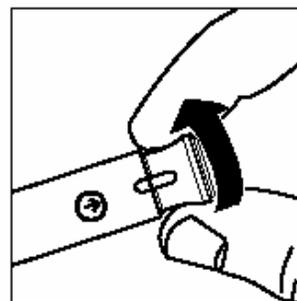


5. **Remove the inner needle shield and discard.**

III. Priming the Pen

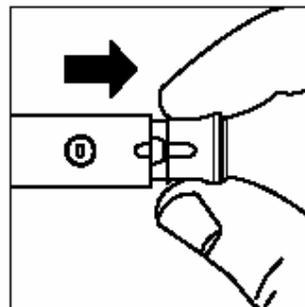
- **Always use a new needle for each injection.**
- **The Pen must be primed before each injection to make sure the Pen is ready to dose.**
Performing the priming step is important to confirm that insulin comes out when you push the injection button, and to remove air that may collect in the insulin 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.

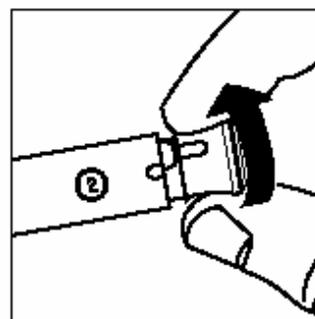


III. Priming the Pen (Continued)

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.

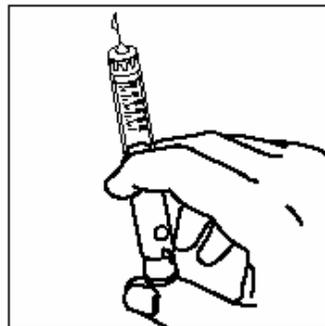


3. Turn the dose knob clockwise until the number “2” is seen in the dose window. If the number you have dialed is too high, simply turn the dose knob backward until the number 2 is seen in the dose window.



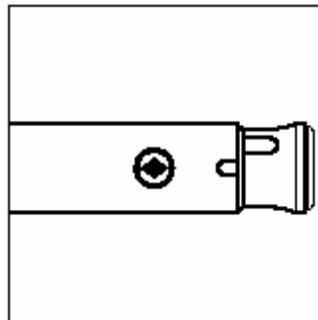
III. Priming the Pen (Continued)

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.

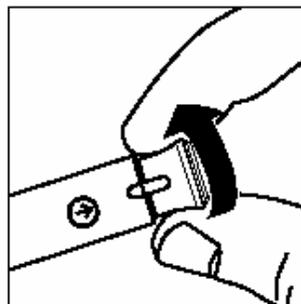
6. Now you are ready to set your dose. See next page.

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.

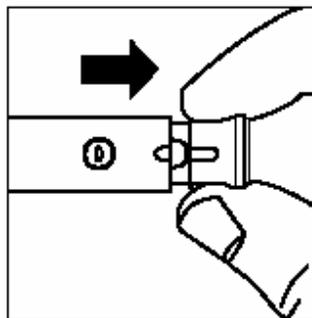
2. Turn the dose knob clockwise until the arrow (→) is seen in the dose window and the notches on the Pen and dose knob are in line.



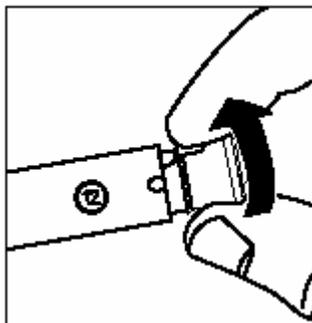
* See Page 16.

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

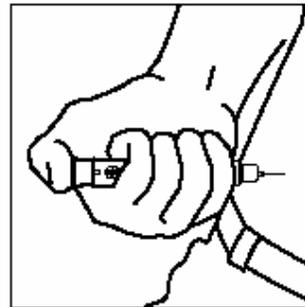
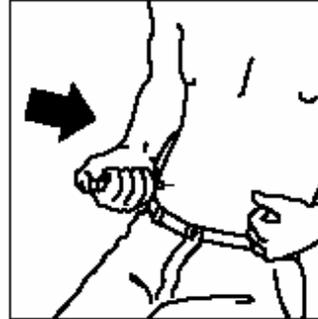
- **Always use a new needle for each injection. Storing the Pen with the needle attached may allow insulin to leak from the Pen and air bubbles to form in the cartridge.**
- **Caution: Do not attempt to change the dose after you begin to push in the injection button. Failure to follow these instructions 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 a 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.

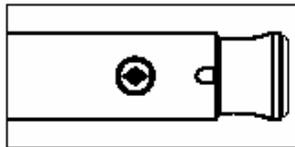
Inject the insulin by using your thumb, if possible, to completely push in the injection button. When the injection button has been completely pushed in (**a diamond (♦) or arrow (→) must be seen in the dose window to indicate that the injection button has been completely pushed in**), continue to hold 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.



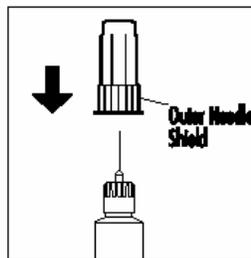
VI. Following an Injection

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.

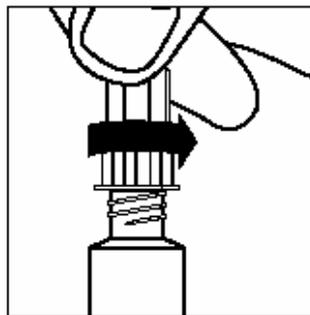


2. Carefully replace the **outer needle shield**.

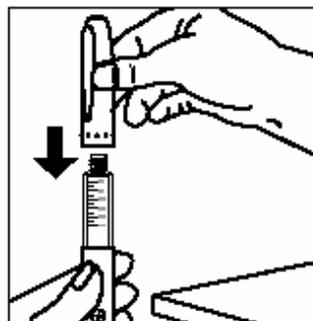


VI. Following an Injection (Continued)

3. Remove the capped needle by turning it counterclockwise and dispose of it as directed by your Health Care Professional. 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 using should **NOT** be refrigerated but kept at room temperature [below 86°F (30°C)] and away from direct 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.	The Pen will not allow you to dial a dose greater than the number of insulin units remaining in the cartridge. 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: 1) Give the partial dose and then give the remaining dose using a new Pen, or 2) Give the full dose with a new Pen.
A small amount of insulin remains in the cartridge but a dose cannot be dialed.	The Pen design prevents the cartridge from being completely emptied. The Pen has delivered 300 units of usable insulin.

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,
1-888-88-LILLY**

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Eli Lilly and Company, Indianapolis, IN 46285, USA

A3.0 NL 3730 AMP

PRINTED IN USA

Control No.:

Exp Date:

Lilly

NDC 0002-8730-01
3 mL HP 8730

Humulin[®] N Pen

*NPH
human insulin
(rDNA origin)
isophane suspension*

100 Units per mL

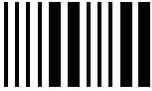
disposable insulin delivery device



U-100

Eli Lilly and Company, Indianapolis, IN 46285, USA

W W 9 1 9 0 A M X



Exp. Date / Control No.

5 x 3 mL disposable insulin delivery devices

NDC 0002-8730-59
HP 8730
100 Units per mL



Humulin® N Pen

NPH
human insulin
(rDNA origin)
isophane suspension
disposable insulin delivery device

U-100



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

3 mL 5 x 3 mL disposable insulin delivery devices
100 Units per mL



Humulin® N Pen

NPH
human insulin
(rDNA origin)
isophane suspension

HP 8730

U-100

disposable insulin delivery device

FC 2491 AMS

3 mL



5 x 3 mL disposable insulin delivery devices
100 Units per mL

HP 8730

Humulin® N Pen

NPH
human insulin
(rDNA origin)
isophane suspension

U-100

disposable insulin delivery device
For information call 1-888-885-4559

FC 2491 AMS
FC 2491 AMS

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.

Contains Metacresol 0.16% and Phenol 0.065% added during manufacture as preservatives.



Eli Lilly and Company
Indianapolis, IN 46285, USA
1-888-885-4559

IMPORTANT-SEE WARNINGS ON
ENCLOSED INSERT



3 0002-8730-59 1

If the seal is broken before first use, contact pharmacist

3 mL
5 x 3 mL disposable insulin delivery devices
100 Units per mL
NPH
human insulin
(rDNA origin)
isophane suspension
Humulin® N Pen

HP 8730
 U-100
disposable insulin delivery device

C-1004