1		2.0 PV 3682 AMP
2	INFORMATION FOR THE PATIENT	
3	3 ML DISPOSABLE INSULIN DELIVERY DEVICE	
4	HUMULIN <sup>®</sup> N Pen	
5	NPH	
6	HUMAN INSULIN	
		NI .
7		N
8	100 UNITS PER ML (U-100)	
9 10	<u>WARNINGS</u> THIS LILLY HUMAN INSULIN PRODUCT DIFFERS FROM A	A NILVE A L
10	SOURCE INSULINS BECAUSE IT IS STRUCTURALLY IDENT	
12	<b>INSULIN PRODUCED BY YOUR BODY'S PANCREAS AND BE</b>	
13	UNIQUE MANUFACTURING PROCESS.	
14	ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUS	
15	UNDER MEDICAL SUPERVISION. CHANGES IN STRENGTH,	
16 17	MANUFACTURER, TYPE (E.G., REGULAR, NPH, LENTE, ETC (BEEF, PORK, BEEF-PORK, HUMAN), OR METHOD OF MAN	.), SPECIES LIFACTURE
18	(rDNA VERSUS ANIMAL-SOURCE INSULIN) MAY RESULT I	N THE NEED
19	FOR A CHANGE IN DOSAGE.	
20	SOME PATIENTS TAKING HUMULIN <sup>®</sup> (HUMAN INSULIN, 1 MAY REQUIRE A CHANGE IN DOSAGE FROM THAT USED <b>V</b>	DNA ORIGIN)
21	MAY REQUIRE A CHANGE IN DOSAGE FROM THAT USED	WITH
22 23	ANIMAL-SOURCE INSULINS. IF AN ADJUSTMENT IS NEEDE OCCUR WITH THE FIRST DOSE OR DURING THE FIRST SET	LD, IT MAY Vedal weeks
23	OR MONTHS.	VERAL WEEKS
25	TO OBTAIN AN ACCURATE DOSE, CAREFULLY READ AN	D FOLLOW
26	THE "DISPOSABLE INSULIN DELIVERY DEVICE USER MAN	NUAL" AND
27	THIS "INFORMATION FOR THE PATIENT" INSERT BEFORE	E USING THIS
28	PRODUCT.	
29	<b>BEFORE EACH INJECTION, YOU SHOULD PRIME THE PE</b>	N, A
30 31	NECESSARY STEP TO MAKE SURE THE PEN IS READY TO I PRIMING THE PEN IS IMPORTANT TO CONFIRM THAT INS	DOSE.
32	OUT WHEN YOU PUSH THE INJECTION BUTTON AND TO R	
33	THAT MAY COLLECT IN THE INSULIN CARTRIDGE DURIN	<b>G NORMAL</b>
34	USE. IF YOU DO NOT PRIME, YOU MAY RECEIVE TOO MUC	
35	LITTLE INSULIN (see also INSTRUCTIONS FOR INSULIN PEN	VUSE section).
36	DIABETES	1 1 771
37 38	Insulin is a hormone produced by the pancreas, a large gland that lies near t hormone is necessary for the body's correct use of food, especially sugar. Dia	he stomach. This
38 39	the pancreas does not make enough insulin to meet your body's needs.	beles occurs when
40	To control your diabetes, your doctor has prescribed injections of insulin pr	oducts to keep your
41	blood glucose at a near-normal level. You have been instructed to test your bl	ood and/or your
42	urine regularly for glucose. Studies have shown that some chronic complication	ons of diabetes
43 44	such as eye disease, kidney disease, and nerve disease can be significantly rec sugar is maintained as close to normal as possible. The American Diabetes As	ssociation
45	recommends that if your pre-meal glucose levels are consistently above 130 n	ng/dL or your
46	hemoglobin A1c (HbA1c) is more than 7%, consult your doctor. A change in	your diabetes

therapy may be needed. If your blood tests consistently show below-normal glucose levels, you
should also let your doctor know. Proper control of your diabetes requires close and constant

49 cooperation with your doctor. Despite diabetes, you can lead an active and healthy life if you eat

50 a balanced diet, exercise regularly, and take your insulin injections as prescribed.

Always keep an extra supply of insulin as well as a spare syringe and needle on hand. Always

- 52 wear diabetic identification so that appropriate treatment can be given if complications occur
- 53 away from home.
- 54

# NPH HUMAN INSULIN

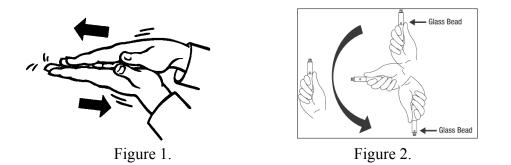
# 55 **Description**

Humulin is synthesized in a non-disease-producing special laboratory strain of *Escherichia coli* bacteria that has been genetically altered by the addition of the human gene for insulin production. Humulin<sup>®</sup> N (human insulin [rDNA origin] isophane suspension) is a crystalline suspension of human insulin with protamine and zinc providing an intermediate-acting insulin with a slower onset of action and a longer duration of activity (up to 24 hours) than that of regular insulin. The time course of action of any insulin may vary considerably in different individuals or at different times in the same individual. As with all insulin preparations, the

- duration of action of Humulin N is dependent on dose, site of injection, blood supply,
- 64 temperature, and physical activity. Humulin N is a sterile suspension and is for subcutaneous
- 65 injection only. It should not be used intravenously or intramuscularly. The concentration of
- 66 Humulin N in Humulin N Pen is 100 units/mL (U-100).

# 67 Identification

- 68 Humulin disposable insulin delivery devices, by Eli Lilly and Company, are available in
- 69 2 formulations NPH and 70/30.
- Your doctor has prescribed the type of insulin that he/she believes is best for you. DO NOT
   USE ANY OTHER INSULIN EXCEPT ON HIS/HER ADVICE AND DIRECTION.
- The Humulin N Pen is available in boxes of 5 disposable insulin delivery devices ("insulin
- 73 Pens"). The Humulin N Pen is not designed to allow any other insulin to be mixed in its
- 74 cartridge, or for the cartridge to be removed.
- 75 Always examine the appearance of Humulin N suspension in the insulin Pen before
- administering a dose. A cartridge of Humulin N contains a small glass bead to assist in mixing.
- 77 Humulin N Pen must be rolled between the palms 10 times and inverted 180° 10 times before
- each injection so that the contents are uniformly mixed (*see* Figures 1 and 2). Inspect the
- 79 Humulin N suspension for uniform mixing and repeat the above steps as necessary.
- 80



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

87	Always check the appearance of the Humulin N suspension in the insulin Pen before using,
88	and if you note anything unusual in the appearance of Humulin N suspension or notice your
89	insulin requirements changing markedly, consult your doctor.
90	Never attempt to remove the cartridge from the Humulin N Pen. Inspect the cartridge through
91	the clear cartridge holder.
92	Storage
93	<b>Not in-use (unopened):</b> Humulin N Pens not in-use should be stored in a refrigerator but not
94	in the freezer. Do not use Humulin N Pen if it has been frozen.
95	<b>In-use:</b> Humulin N Pens in-use should <b>NOT</b> be refrigerated but should be kept at room
96	temperature (below 86°F [30°C]) away from direct heat and light. Humulin N Pens in-use must
97	be discarded after 2 weeks, even if they still contain Humulin N.
98	Do not use Humulin N Pens after the expiration date stamped on the label.
99	INSTRUCTIONS FOR INSULIN PEN USE
100 101	It is important to read, understand, and follow the instructions in the "Disposable Insulin Delivery Device User Menuel" before using Failure to follow instructions may result in
101	Delivery Device User Manual" before using. Failure to follow instructions may result in getting too much or too little insulin. The needle must be changed and the Pen must be
102	primed before each injection to make sure the Pen is ready to dose. Performing these steps
105	before each injection is important to confirm that insulin comes out when you push the
105	injection button, and to remove air that may collect in the insulin cartridge during normal
106	use.
107	Every time you inject:
108	• Use a new needle.
100	<ul> <li>Prime to make sure the Pen is ready to dose.</li> </ul>
110	Make sure you got your full dose.
111	NEVER SHARE INSULIN PENS, CARTRIDGES, OR NEEDLES.
112 113	PREPARING THE INSULIN PEN FOR INJECTION
113	1. Always check the appearance of the Humulin N suspension in the insulin Pen before using.
115	<ol> <li>Roll the Humulin N Pen between the palms 10 times (<i>see</i> Figure 1).</li> </ol>
116	<ol> <li>Kon the Humulin N Pen by one end, invert it 180° slowly 10 times to allow the small</li> </ol>
117	glass bead to travel the full length of the cartridge with each inversion (see Figure 2). The
118	cartridge is contained in the clear cartridge holder of the Humulin N Pen.
119	4. Inspect the appearance of the Humulin N suspension to make sure the contents look
120	uniformly cloudy or milky. If not, repeat the above steps until the contents are mixed. Do
121	not use a Humulin N Pen if there are clumps in the insulin or if solid white particles stick
122	to the walls of the cartridge.
123	5. Follow the instructions in the "Disposable Insulin Delivery Device User Manual" for
124	these steps:
125	• Preparing the Pen
126	• Attaching the Needle. Use a new needle for each injection.
127	• Priming the Pen. The Pen must be primed before each injection to make sure the
128	Pen is ready to dose. Performing the priming step is important to confirm that insulin
129	comes out when you push the injection button, and to remove air that may collect in
130	the insulin cartridge during normal use.
131	Setting a Dose
132	• Injecting a Dose. To make sure you have received your full dose, you must push
133	the injection button all the way down until you see a diamond $(\blacklozenge)$ or an arrow
134	$(\rightarrow)$ in the center of the dose window.
135	Following an Injection     PREPARING FOR INJECTION
136 137	
17/	1. Wash your hands.

- To avoid tissue damage, choose a site for each injection that is at least 1/2 inch from the previous injection site. The usual sites of injection are abdomen, thighs, and arms.
- 140 3. Cleanse the skin with alcohol where the injection is to be made.
- 141 4. With one hand, stabilize the skin by spreading it or pinching up a large area.
- 142
  5. Inject the dose as instructed by your doctor. Hold the needle under the skin for at least 5 seconds after injecting.
- After injecting a dose, pull the needle out and apply gentle pressure over the injection site
  for several seconds. Do not rub the area.
- Immediately after an injection, remove the needle from the Humulin N Pen. Doing so will
   guard against contamination, leakage, reentry of air, and needle clogs. Do not reuse
   needles. Place the used needle in a puncture-resistant disposable container and properly
   dispose of it as directed by your Health Care Professional.
- 150

- DOSAGE
- 151 Your doctor has told you which insulin to use, how much, and when and how often to inject it. 152 Because each patient's case of diabetes is different, this schedule has been individualized for you.
- 153 Your usual Humulin N dose may be affected by changes in your food, activity, or work
- 154 schedule. Carefully follow your doctor's instructions to allow for these changes. Other things that 155 may affect your Humulin N dose are:

#### 156 Illness

157 Illness, especially with nausea and vomiting, may cause your insulin requirements to change. 158 Even if you are not eating, you will still require insulin. You and your doctor should establish a 159 sick day plan for you to use in case of illness. When you are sick, test your blood glucose/urine 160 glucose and ketones frequently and call your doctor as instructed.

### 161 **Pregnancy**

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

#### 165 Medication

Insulin requirements may be increased if you are taking other drugs with hyperglycemic
 activity, such as oral contraceptives, corticosteroids, or thyroid replacement therapy. Insulin
 requirements may be reduced in the presence of drugs with blood-glucose-lowering activity,

such as oral antidiabetic agents, salicylates (for example, aspirin), sulfa antibiotics, alcohol, and

170 certain antidepressants. Always discuss any medications you are taking with your doctor.

# 171 Exercise

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

170 exercise

# 177 **Travel**

Persons traveling across more than 2 time zones should consult their doctor concerningadjustments in their insulin schedule.

180

184

# COMMON PROBLEMS OF DIABETES

# 181 Hypoglycemia (Low Blood Sugar)

- Hypoglycemia (too little glucose in the blood) is one of the most frequent adverse events
  experienced by insulin users. It can be brought about by:
  - 1. Taking too much insulin.
- 185 2. Missing or delaying meals.
- 186 3. Exercising or working more than usual.
- 187 4. An infection or illness (especially with diarrhea or vomiting).

5

- 188 5. A change in the body's need for insulin.
- 189
  189 Diseases of the adrenal, pituitary or thyroid gland, or progression of kidney or liver disease.
- 191
   7. Interactions with other drugs that lower blood glucose, such as oral antidiabetic agents, salicylates (for example, aspirin), sulfa antibiotics, and certain antidepressants.
  - 8. Consumption of alcoholic beverages.

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

195 • sweating

193

201

206

207

237

- 196 dizziness
- 197 palpitation
- 198 tremor
- 199 hunger
- restlessness
  - tingling in the hands, feet, lips, or tongue
- lightheadedness
- inability to concentrate
- headache
- 205 Signs of severe hypoglycemia can include:
  - disorientation
    - unconsciousness
- 208 Therefore, it is important that assistance be obtained immediately.
- Early warning symptoms of hypoglycemia may be different or less pronounced under certain conditions, such as long duration of diabetes, diabetic nerve disease, medications such as betablockers, change in insulin preparations, or intensified control (3 or more insulin injections per day) of diabetes.

A few patients who have experienced hypoglycemic reactions after transfer from animalsource insulin to human insulin have reported that the early warning symptoms of hypoglycemia were less pronounced or different from those experienced with their

216 previous insulin.

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

- Mild to moderate hypoglycemia may be treated by eating foods or drinks that contain sugar. Patients should always carry a quick source of sugar, such as candy mints or glucose tablets.
- 224 Patients should always carry a quick source of sugar, such as candy mints of glucose tablets. 225 More severe hypoglycemia may require the assistance of another person. Patients who are unable
- to take sugar orally or who are unconscious require an injection of glucagon or should be treated with intravenous administration of glucose at a medical facility.
- You should learn to recognize your own symptoms of hypoglycemia. If you are uncertain about these symptoms, you should monitor your blood glucose frequently to help you learn to recognize the symptoms that you experience with hypoglycemia.
- 231 If you have frequent episodes of hypoglycemia or experience difficulty in recognizing the
- symptoms, you should consult your doctor to discuss possible changes in therapy, meal plans,
   and/or exercise programs to help you avoid hypoglycemia.

# 234 Hyperglycemia and Diabetic Ketoacidosis (DKA)

- Hyperglycemia (too much glucose in the blood) may develop if your body has too little insulin.
  Hyperglycemia can be brought about by:
  - 1. Omitting your insulin or taking less than the doctor has prescribed.

- drowsiness sleep disturbances
  - sleep distuiba
  - anxiety
  - blurred vision
  - slurred speech
  - depressed mood
  - irritability
  - abnormal behavior
  - unsteady movement
  - personality changes
  - seizures
  - death

- 238 Eating significantly more than your meal plan suggests. 2. 239
  - 3. Developing a fever, infection, or other significant stressful situation.

In patients with type 1 or insulin-dependent diabetes, prolonged hyperglycemia can result in 240 DKA. The first symptoms of DKA usually come on gradually, over a period of hours or days, 241 and include a drowsy feeling, flushed face, thirst, loss of appetite, and fruity odor on the breath. 242 243 With DKA, urine tests show large amounts of glucose and ketones. Heavy breathing and a rapid 244 pulse are more severe symptoms. If uncorrected, prolonged hyperglycemia or DKA can lead to nausea, vomiting, stomach pains, dehydration, loss of consciousness or death. Therefore, it is 245 246 important that you obtain medical assistance immediately.

#### 247 Lipodystrophy

248 Rarely, administration of insulin subcutaneously can result in lipoatrophy (depression in the 249 skin) or lipohypertrophy (enlargement or thickening of tissue). If you notice either of these 250 conditions, consult your doctor. A change in your injection technique may help alleviate the 251 problem.

#### Allergy to Insulin 252

253 Local Allergy — Patients occasionally experience redness, swelling, and itching at the site of injection of insulin. This condition, called local allergy, usually clears up in a few days to a few 254 255 weeks. In some instances, this condition may be related to factors other than insulin, such as 256 irritants in the skin cleansing agent or poor injection technique. If you have local reactions, 257 contact your doctor.

258 Systemic Allergy — Less common, but potentially more serious, is generalized allergy to 259 insulin, which may cause rash over the whole body, shortness of breath, wheezing, reduction in 260 blood pressure, fast pulse, or sweating. Severe cases of generalized allergy may be life 261 threatening. If you think you are having a generalized allergic reaction to insulin, notify a doctor 262 immediately.

- ADDITIONAL INFORMATION
- 263 264 Additional information about diabetes may be obtained from your diabetes educator.

DIABETES FORECAST is a magazine designed especially for people with diabetes and their 265 families. It is available by subscription from the American Diabetes Association, P.O. Box 363, 266 267 Mt. Morris, IL 61054-0363, 1-800-DIABETES (1-800-342-2383).

- 268 Another publication, **COUNTDOWN**, is available from the Juvenile Diabetes Research 269 Foundation International (JDRFI), 120 Wall Street 19th Floor, New York, NY 10005,
- 270 1-800-533-CURE (1-800-533-2873).
- 271 Additional information about Humulin and Humulin N Pens can be obtained by calling The 272 Lilly Answers Center at 1-800-LillyRx (1-800-545-5979).
- Literature revised Month dd, 2004 273

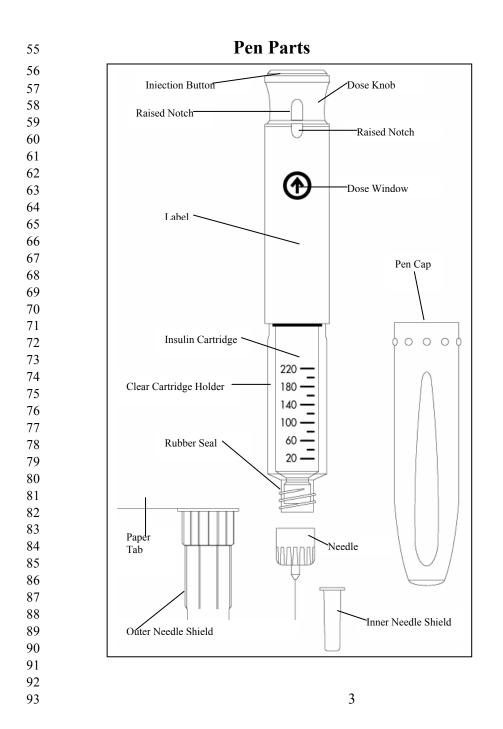
#### 274 Eli Lilly and Company, Indianapolis, IN 46285, USA

275 2.0 PV 3682 AMP 276

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	Lilly	
	Disposable Insulin Delivery Devi	ce
	User Manual	
Instruct	tions for Use	
	follow all of these instructions carefully. If you do n y, you may get too much or too little insulin.	ot follow these instructio
Everv tim	e 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)	~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~
		6
	the "INFORMATION FOR THE PATIENT"	/ /
insert enc	losed in your Pen box.	6/
Pen Featu	res	
	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	S
•	Doses can be dialed by single units	

F	Pen Parts
[	mportant Notes
F	Preparing the Pen
F	Attaching the Needle
F	Priming the Pen 1
	letting a Dose 1
ſ	njecting a Dose 1
F	Collowing an Injection 1
(	Questions and Answers



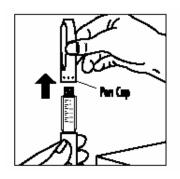
94		
95		Important Notes
96 97 98	•	Read and follow all of these instructions carefully. If you do not follow these instructions completely, you may get too much or too little insulin.
99		
100 101	•	Use a new needle for each injection.
102 103 104		• Be sure a needle is completely attached to the Pen before priming, setting the dose and injecting your insulin.
105 106	•	Prime every time.
107 108 109 110 111		• 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.
111 112 113		• If you do not prime, you may get too much or too little insulin.
114 115	•	Make sure you get your full dose.
116 117 118 119		• 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.
120 121 122	•	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.
122 123 124	•	Do not share your Pen.
125 126		4

127		Important Notes
128		(Continued)
129		
130	٠	Keep your Pen out of the reach of children.
131		
132	٠	Pens that have not been used (unopened) should be stored in a refrigerator but not in a
133		freezer. Do not use a Pen if it has been frozen. Refer to the "INFORMATION FOR THE
134		PATIENT" insert for complete storage instructions.
135		
136	•	After a Pen is used for the first time, it should <b>NOT</b> be refrigerated but should be kept at $P_{\text{NOT}}$ to the should be kept at $P_{\text{NOT}}$ be refrigerated but should be kept at $P_{\text{NOT}}$ be refrine the refrine the refrigerated but should be kept at $P$
137 138		room temperature [below 86°F (30°C)] and away from direct heat and light.
138	•	An unrefrigerated Pen should be discarded according to the time specified in the
140	•	"INFORMATION FOR THE PATIENT" insert, even if it still contains insulin.
141		
142	•	Never use a Pen after the expiration date stamped on the label.
143		
144	٠	Do not store your Pen with the needle attached. Doing so may allow insulin to leak from the
145		Pen and air bubbles to form in the cartridge. Additionally, with suspension (cloudy) insulins,
146		crystals may clog the needle.
147		
148	•	Always carry an extra Pen in case yours is lost or damaged.
149 150	•	Dispose of empty Pens as instructed by your Health Care Professional and without the needle
150	•	attached.
151		
153	•	This Pen is not recommended for use by blind or visually impaired patients without the
154		assistance of a person trained in the proper use of the product.
155		
156	٠	The directions regarding needle handling are not intended to replace local, Health Care
157		Professional, or institutional policies.
158		
159	٠	Any changes in insulin should be made cautiously and only under medical supervision.
160		
161 162		5
102		

6

# I. Preparing the Pen Before proceeding, refer to the "INFORMATION FOR THE PATIENT" insert for instructions on checking the appearance of your insulin. Check the label on the Pen to be sure the Pen contains the type of insulin that has been prescribed for you. Always wash your hands before preparing your Pen for use.

- 165
- 4. Pull the Pen cap to remove.



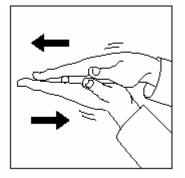
166 167

# I. Preparing the Pen (Continued)

169 170

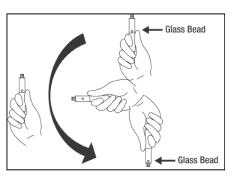
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- 5. If your insulin is a suspension (cloudy):
  - a. Roll the Pen back and forth 10 times then perform step b.



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

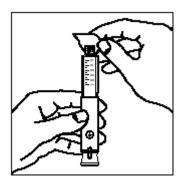
**Note:** Suspension (cloudy) insulin cartridges contain a small glass bead to assist in mixing.



172 173

171

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

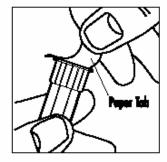


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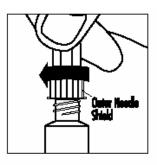
176	II. Attaching the Needle
177	
178	This device is suitable for use with Becton Dickinson and Company's insulin pen needles.
179 180	
	1. Always use a new needle for each injection. Do not push injection button without a needle attached. Storing the Pen with the needle attached may allow insulin to leak from the Pen and air bubbles to form in the cartridge.
181	

2. Remove the paper tab from the outer needle shield.



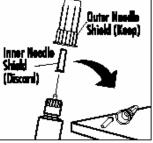
182

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



183 184

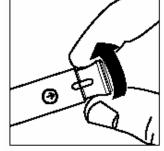
185 186		II. Attaching the Needle (Continued)	
187	4.	Hold the Pen with the needle pointing up and remove the <b>outer needle shield. Keep it to use during needle removal.</b>	Inner Headle



188		
	5.	Remove the inner needle shield and discard.
189		
190		
191		9

192		III. Priming the Pen				
193						
194	٠	The Pen must be primed before each injection to make sure the Pen is ready to dose.				
195		Performing the priming step is important to confirm that insulin comes out when you push the				
196		injection button, and to remove air that may collect in the insulin cartridge during normal use.				
197						
198	٠	If you do not prime, you may get too much or too little insulin.				
199						
200	٠	Always use a new needle for each injection.				
201						
	1.	Make sure the arrow is in the center of the dose window as				

shown.



202 203 204 205 206 207 208 209 210	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.	
211 212		10	

Correct

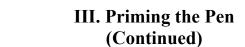
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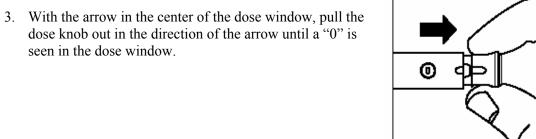
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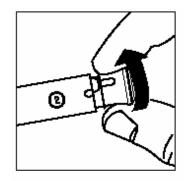
214 215

> 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.

seen in the dose window.







217 218

219 220		III. Priming the Pen	
221		(Continued)	
222			
	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 thumh if possible much in the injection	1234.

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** 226 (Continued) 227 228 6. At the completion of the priming step, a diamond  $(\bullet)$  must be seen in the center of the dose window. ۲ If a diamond  $(\blacklozenge)$  is not seen in the center of the dose window, continue pushing on the injection button until you see a diamond  $(\blacklozenge)$  in the center of the dose window. 229 230 231 232 233 234 235 Correct

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

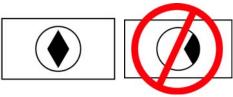
7. Now you are ready to set your dose. See next page.

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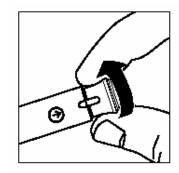
238		IV Catt's a Dam
239		IV. Setting a Dose
240		
241	•	Always use a new needle for each injection. Storing the Pen with the needle attached
242		may allow insulin to leak from the Pen and air bubbles to form in the cartridge.
243		
244	٠	Caution: Do not push in the injection button while setting your dose. Failure to follow
245		these instructions carefully may result in getting too much or too little insulin. If you
246		accidentally push the injection button while setting your dose, you must prime the Pen
247		again before injecting your dose. See Section III. "Priming the Pen", pages 10-13.
248		
	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.



Correct

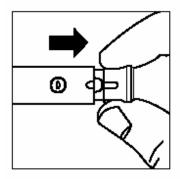
2. Turn the dose knob clockwise until the arrow  $(\rightarrow)$  is seen in the center of the dose window and the notches on the Pen and dose knob are in line.



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# IV. Setting a Dose (Continued)

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.

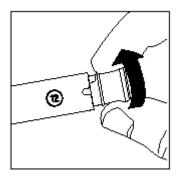


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4. Turn the dose knob clockwise until your dose is seen in the dose window. If the dose you have dialed is too high, simply turn the dose knob backward until the correct dose is seen in the dose window.



#### 256

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

257

<ul> <li>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.</li> <li>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.</li> </ul>	258	V. Injecting a Dose
<ul> <li>261 may allow insulin to leak from the Pen and air bubbles to form in the cartridge.</li> <li>262</li> <li>263 Caution: Do not attempt to change the dose after you begin to push in the injection</li> <li>264 button. Failure to follow these instructions carefully may result in getting too much or</li> <li>265 too little insulin.</li> </ul>	259	
<ul> <li>262</li> <li>263</li> <li>Caution: Do not attempt to change the dose after you begin to push in the injection</li> <li>264</li> <li>button. Failure to follow these instructions carefully may result in getting too much or</li> <li>265</li> <li>too little insulin.</li> </ul>	260 •	Always use a new needle for each injection. Storing the Pen with the needle attached
<ul> <li>Caution: Do not attempt to change the dose after you begin to push in the injection</li> <li>button. Failure to follow these instructions carefully may result in getting too much or</li> <li>too little insulin.</li> </ul>	261	may allow insulin to leak from the Pen and air bubbles to form in the cartridge.
<ul> <li>button. Failure to follow these instructions carefully may result in getting too much or</li> <li>too little insulin.</li> </ul>	262	
265 too little insulin.	263 •	
	264	
	265	too little insulin.
	266	
• The effort needed to push in the injection button may increase while you are injecting		
268 your insulin dose. If you cannot completely push in the injection button, refer to the		
269 "Questions and Answers" section, Question 7, at the end of this manual.		"Questions and Answers" section, Question 7, at the end of this manual.
270		
272 or too little insulin.		or too little insulin.
• If you have set a dose and pushed in the injection button without a needle attached or if no		5 1 5
		insulin comes out of the needle, see the "Questions and Answers" section, Questions 1 and 2.
276		16
277 16	211	10

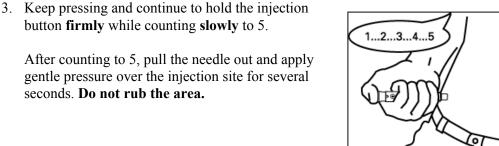
# V. Injecting a Dose (Continued)

- 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.

button firmly while counting slowly to 5.

seconds. Do not rub the area.





283 284 285 4. When the injection is done, a diamond  $(\blacklozenge)$  or arrow  $(\rightarrow)$  must be seen in the center of the 286 dose window. This means your full dose has 287 been delivered. If you do not see the diamond 288 or arrow in the center of the dose window, 289 290 you did not get your full dose. Contact your Health Correct for additional 291 instruction. 292 293 294 295 296 Correct 297 298

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#### 18

# **VI.** Following an Injection

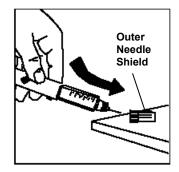
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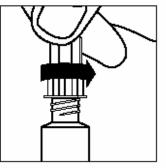
- Make sure you got your full dose by checking that the injection button has been completely pushed in and you can see a diamond (♦) or arrow (→) in the center of the dose window. If you do not see the diamond (♦) or arrow (→) in the center of the dose window, you have not received your full dose. Contact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

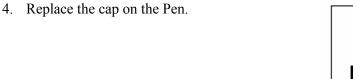


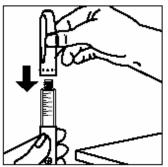


# VI. Following an Injection (Continued)

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.







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- 5. The Pen that you are using should **NOT** be refrigerated but should be 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.

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318 Do not store or dispose of the Pen with a needle attached. Storing the Pen with the needle 319 attached may allow insulin to leak from the Pen and air bubbles to form in the cartridge. 320

- 321
- 322

Problem	uestions and Answers Action	
<ol> <li>Dose dialed and injection button pushed in without a needle attached.</li> </ol>	<ul> <li>To obtain an accurate dose you must:</li> <li>1) Attach a new needle.</li> <li>2) Push in the injection button completely (even if a "0" is seen in the window) until a diamond (♦) or arrow (→) is seen in the center of the dose window</li> <li>3) Prime the Pen.</li> </ul>	
2. Insulin does not come out of the needle.	<ul> <li>To obtain an accurate dose you must:</li> <li>1) Attach a new needle.</li> <li>2) Push in the injection button completely (even if a "0" is seen in the window) until a diamond (♦) or arrow (→) is seen in the center of the dose window</li> <li>3) Prime the Pen. See Section III. "Priming the Pen", pages 10-13.</li> </ul>	

Pr	oblem	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.	<ul> <li>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:</li> <li>1) Give the partial dose and then give the remaining dose using a new Pen, or</li> <li>2) Give the full dose with a new Pen.</li> </ul>
6. 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.

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)	Questions and Answers (Continued)			
P	<b>roblem</b> . Cannot completely push in the injection button when priming the Pen or injecting a dose.	<ul> <li>Action</li> <li>1) Needle is not attached or is clogged.</li> <li>a. Attach a new needle.</li> <li>b. Push in the injection button completely (even if a "0" is seen in the window) until a diamond (♦)</li> </ul>		
		<ul> <li>or arrow (→) is seen in the center of the dose window.</li> <li>c. Prime the Pen.</li> <li>2) If you are sure insulin is coming out of the needle, push in the injection button more slowly to reduce the effort needed and maintain a constant pressure until the injection button is completely pushed in.</li> </ul>		
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For additional information call, 1-800-LillyRx (1-800-545-5979)

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