A3.0 NL 3670 AMP

**INFORMATION FOR THE PATIENT**

**3 ML DISPOSABLE INSULIN DELIVERY DEVICE**

# HUMULIN® 70/30 Pen

## 70% HUMAN INSULIN ISOPHANE SUSPENSION AND 30% HUMAN INSULIN INJECTION (rDNA ORIGIN)

**100 UNITS PER ML (U-100)**

## WARNINGS

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

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

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

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

## DIABETES

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

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

recommends that if your premeal glucose levels are consistently above 130 mg/dL or your hemoglobin $A_{1c}$ ($HbA_{1c}$) 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 cooperation with your doctor. Despite diabetes, you can lead an active and healthy life if you eat 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 wear diabetic identification so that appropriate treatment can be given if complications occur away from home.

## 70/30 HUMAN INSULIN

**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® 70/30 is a mixture of 70% Human Insulin Isophane Suspension and 30% Human Insulin Injection, (rDNA origin). It is an intermediate-acting insulin combined with the more rapid onset of action of regular insulin. The duration of activity may last up to 24 hours following injection. 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 70/30 is dependent on dose, site of injection, blood supply, temperature, and physical activity. Humulin 70/30 is a sterile suspension and is for subcutaneous injection only. It should not be used intravenously or intramuscularly. The concentration of Humulin 70/30 in the Humulin 70/30 Pen is 100 units/mL (U-100).

**Identification**

Humulin disposable insulin delivery devices, manufactured by Eli Lilly and Company, are available in 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 70/30 Pen is available in boxes of 5 disposable insulin delivery devices ("insulin Pens"). The Humulin 70/30 Pen is not designed to allow any other insulin to be mixed in its cartridge, or for the cartridge to be removed.

Always examine the appearance of Humulin 70/30 suspension in the insulin Pen before administering a dose. A cartridge of Humulin 70/30 contains a small glass bead to assist in mixing. Humulin 70/30 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 Humulin 70/30 suspension for uniform mixing and repeat the above steps as necessary.

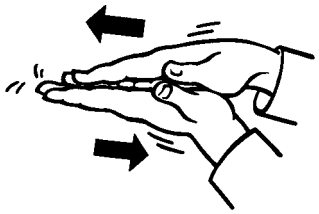

Figure 1.

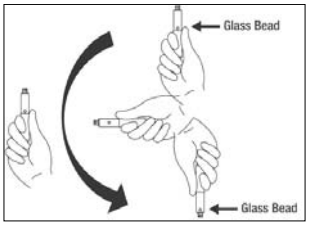


Figure 2.

Humulin 70/30 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 70/30 Pen if there are clumps in the insulin after mixing. Do not use the Humulin 70/30 Pen if solid white particles stick to the walls of the cartridge, giving it a frosted appearance.

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

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

### Storage

**Not in-use (unopened):** Humulin 70/30 Pens not in-use should be stored in a refrigerator but not in the freezer. Do not use Humulin 70/30 Pen if it has been frozen.

**In-use:** Humulin 70/30 Pens in-use should **NOT** be refrigerated but should be kept at room temperature (below 86°F [30°C]) away from direct heat and light. Humulin 70/30 Pens in-use must be discarded **after 10 days**, even if they still contain Humulin 70/30.

Do not use Humulin 70/30 Pens after the expiration date stamped on the label.

## INSTRUCTIONS FOR PEN USE

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

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

**PREPARING THE INSULIN PEN FOR INJECTION:**

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

**PREPARING FOR INJECTION:**

1. Wash your hands.
2. To avoid tissue damage, choose a site for each injection that is at least ½ inch from the previous injection site. The usual sites of injection are abdomen, thighs, and arms.
3. Cleanse the skin with alcohol where the injection is to be made.
4. With one hand, stabilize the skin by spreading it or pinching up a large area.
5. Inject the dose as instructed by your doctor.

6. After dispensing a dose, pull the needle out and apply gentle pressure over the injection site for several seconds. Do not rub the area.
7. Immediately after an injection, remove the needle from the Humulin 70/30 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.

## DOSAGE

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

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

**Illness**

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

**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.

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

**Exercise**

Exercise may lower your body's need for insulin during and for some time after the activity. Exercise may also speed up the effect of an insulin 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.

**Travel**

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

## COMMON PROBLEMS OF DIABETES

**Hypoglycemia (Insulin Reaction)**

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

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

- sweating
- dizziness
- palpitation
- tremor
- hunger
- restlessness
- tingling in the hands, feet, lips, or tongue
- lightheadedness
- inability to concentrate
- headache
- drowsiness
- sleep disturbances
- anxiety
- blurred vision
- slurred speech
- depressed mood
- irritability
- abnormal behavior
- unsteady movement
- personality changes

Signs of severe hypoglycemia can include:

- disorientation
- unconsciousness
- seizures
- death

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 beta-blockers, 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 animal-source insulin to human insulin have reported that the early warning symptoms of hypoglycemia were less pronounced or different from those experienced with their 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 sugar-containing 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. 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.

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.

**Hyperglycemia and Diabetic Acidosis**

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

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

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

**Lipodystrophy**

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

**Allergy to Insulin**

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

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

## ADDITIONAL INFORMATION

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

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

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

Additional information about Humulin and Humulin 70/30 Pen can be obtained by calling 1-888-88-LILLY (1-888-885-4559).

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# Lilly

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

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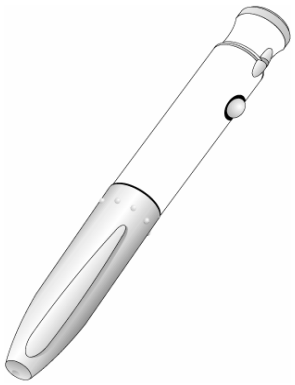
## Instructions for Use

**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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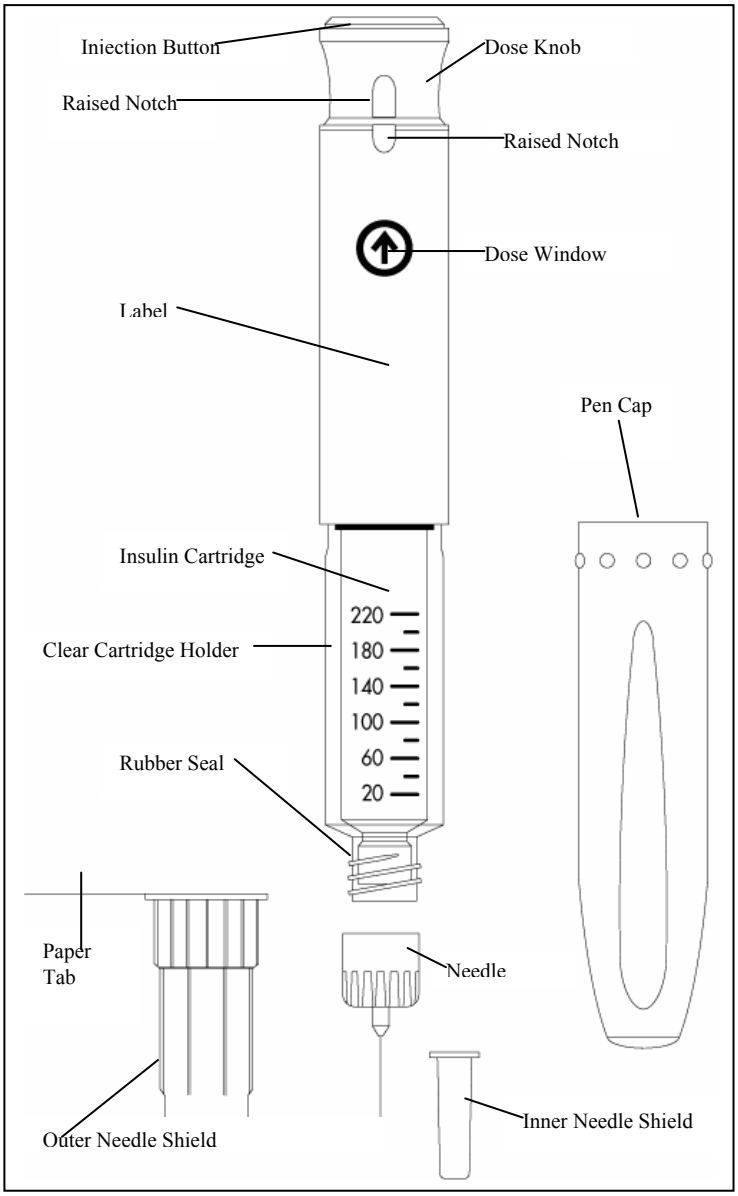
# Pen Parts


Iniection Button
Dose Knob
Raised Notch
Raised Notch
Dose Window
Label
Pen Cap
Insulin Cartridge
220
180
140
100
60
20
Clear Cartridge Holder
Rubber Seal
Paper
Tab
Needle
Inner Needle Shield
Outer Needle Shield

# 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.**

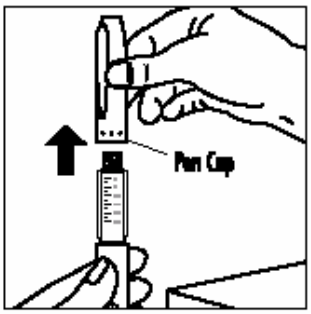
# I. Preparing the Pen

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.

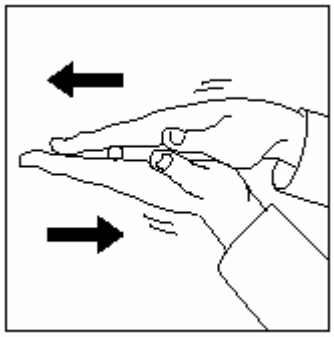
4. Pull the Pen cap to remove.



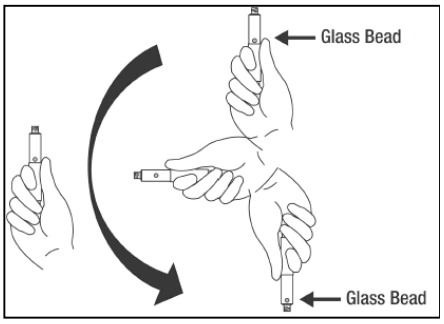
# I. Preparing the Pen (Continued)

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

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

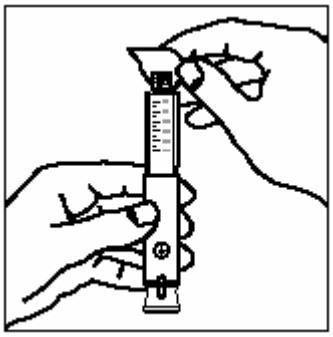


   b. Gently turn the Pen up and down 10 times until the insulin is evenly mixed.




**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.

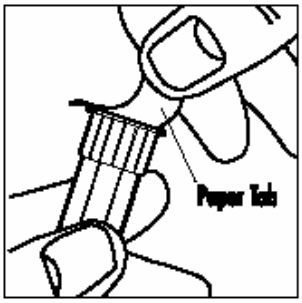


# II. Attaching the Needle

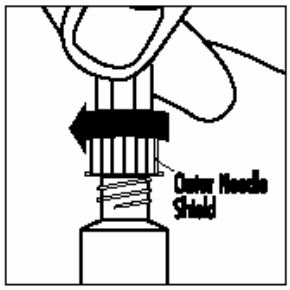
**This device is suitable for use with Becton Dickinson and Company's insulin pen needles.**

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.

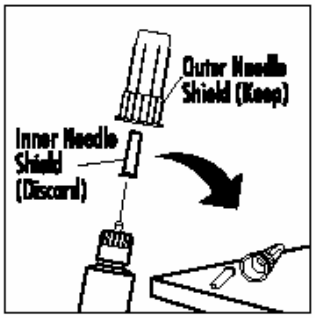



3. Attach the capped needle onto the end of the Pen by turning it clockwise until tight.



# 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.**

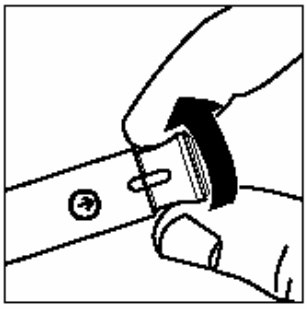
# III. Priming the Pen

- **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.

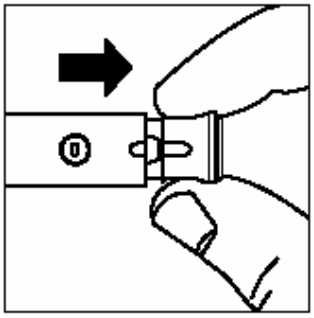
- **If you do not prime, you may receive a wrong dose.**

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.

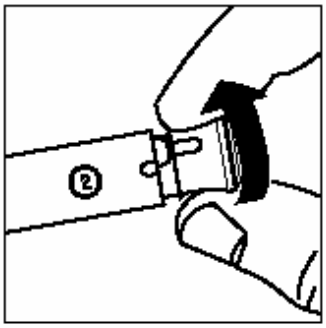


# III. Priming the Pen (Continued)

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.

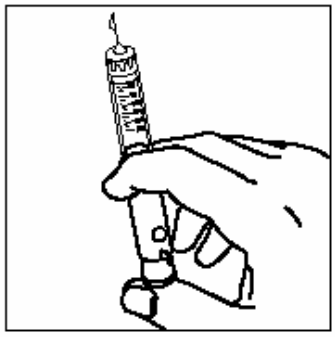



3. Turn the dose knob clockwise until the number “2” is seen in the dose window. If the number you have dialed is too high, simply turn the dose knob backward until the number 2 is seen in the dose window.



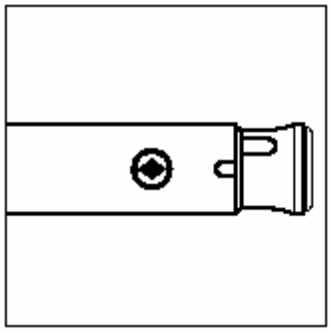
# III. Priming the Pen (Continued)

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.

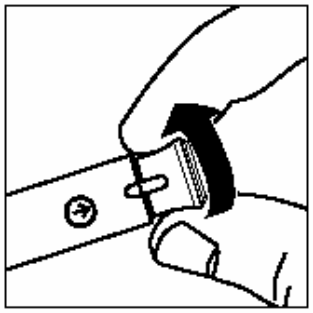
# IV. Setting a Dose

- **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.

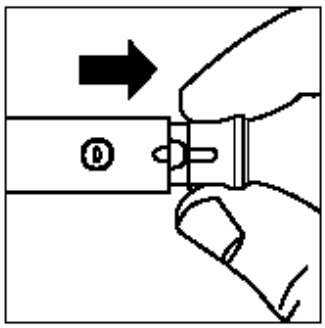
2. Turn the dose knob clockwise until the arrow (→) is seen in the dose window and the notches on the Pen and dose knob are in line.



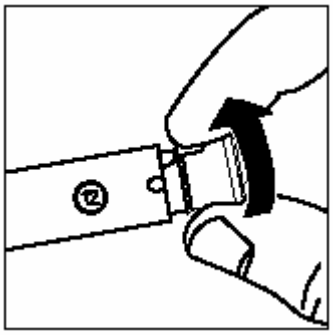
* See Page 16.

# 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.***

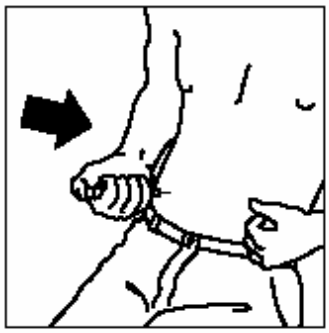
- **The effort needed to push in the injection button may increase while you are injecting your insulin dose. If you cannot completely push in the injection button, refer to the "Questions and Answers" section at the end of this manual.**

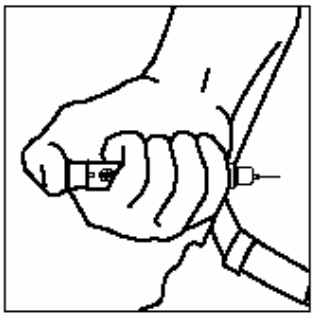
* If you have set (dialed) a dose and pushed in the injection button without a needle attached or if no insulin comes out of the needle, see the "Questions and Answers" section.

# 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.

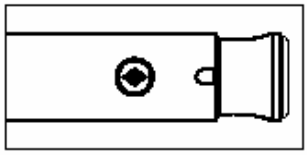




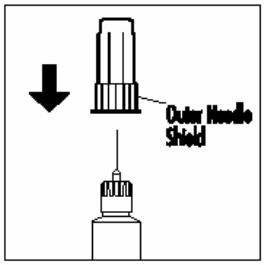
# VI. Following an Injection

**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.

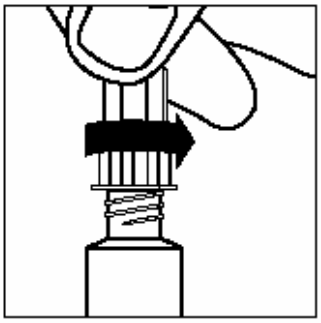


2. Carefully replace the **outer needle shield.**

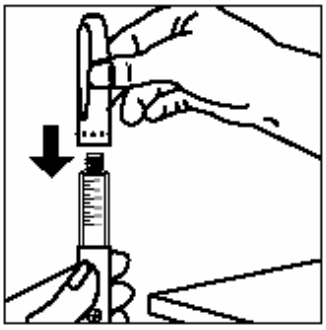


## VI. Following an Injection (Continued)

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:<br>1) Attach a new needle.<br>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.<br>3) Prime the Pen. |
| Insulin does not come out of the needle. | To obtain an accurate dose you must:<br>1) Attach a new needle.<br>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.<br>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:<br>1) Give the partial dose and then give the remaining dose using a new Pen, or<br>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. | 1) Needle is not attached or is clogged.<br>a. Attach a new needle.<br>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.<br>c. Prime the Pen.<br>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**

Literature issued XXX 2003

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

A3.0 NL 3730 AMP PRINTED IN USA

Control No.:

Exp Date:

Lilly

NDC 0002-8770-01
3 mL HP 8770

# Humulin® 70/30 Pen

*70% human insulin isophane suspension*
*30% human insulin injection (rDNA origin)*

**100** Units per mL

*disposable insulin delivery device*

**U-100**

Eli Lilly and Company, Indianapolis, IN 46285, USA

WW9180AMX

Exp. Date / Control No.

U-100

5 x 3 mL disposable insulin delivery devices

NDC 0002-8770-59
HP 8770
100 Units per mL

Lilly

# 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 or their equivalent (needles not included)

3 mL

Lilly

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

Humulin® 70/30 Pen
70% human insulin isophane suspension
30% human insulin injection
(rDNA origin)

HP 8770

U-100

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

FC 2481 AMS
FC 2481 AMS

3 mL

Lilly

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

Humulin® 70/30 Pen
70% human insulin isophane suspension
30% human insulin injection
(rDNA origin)

HP 8770

U-100

disposable insulin delivery device

**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 suspension and 30 units human insulin injection (rDNA origin). Metacresol 0.16% and Phenol 0.065% added during manufacture as preservatives.

Lilly

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

**IMPORTANT-SEE WARNINGS ON ENCLOSED INSERT**

3 0002-8770-59 7

If the seal is broken before first use, contact pharmacist

FC 2481 AMS

C-1004