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2 **INFORMATION FOR THE PATIENT**  
3 **10 mL Vial (1000 Units per vial)**

4 **HUMULIN<sup>®</sup> 70/30**  
5 **70% HUMAN INSULIN**  
6 **ISOPHANE SUSPENSION**  
7 **AND**  
8 **30% HUMAN INSULIN INJECTION**  
9 **(rDNA ORIGIN)**  
10 **100 UNITS PER ML (U-100)**

11 **WARNINGS**

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

16 **ANY CHANGE OF INSULIN SHOULD BE MADE CAUTIOUSLY AND ONLY**  
17 **UNDER MEDICAL SUPERVISION. CHANGES IN STRENGTH,**  
18 **MANUFACTURER, TYPE (E.G., REGULAR, NPH, ANALOG), SPECIES, OR**  
19 **METHOD OF MANUFACTURE MAY RESULT IN THE NEED FOR A**  
20 **CHANGE IN DOSAGE.**

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

25 **DIABETES**

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

29 To control your diabetes, your doctor has prescribed injections of insulin products to keep your  
30 blood glucose at a near-normal level. You have been instructed to test your blood and/or your  
31 urine regularly for glucose. Studies have shown that some chronic complications of diabetes such  
32 as eye disease, kidney disease, and nerve disease can be significantly reduced if the blood sugar  
33 is maintained as close to normal as possible. The American Diabetes Association recommends  
34 that if your pre-meal glucose levels are consistently above 130 mg/dL or your hemoglobin A<sub>1c</sub>  
35 (HbA<sub>1c</sub>) is more than 7%, you should talk to your doctor. A change in your diabetes therapy may  
36 be needed. If your blood tests consistently show below-normal glucose levels, you should also let  
37 your doctor know. Proper control of your diabetes requires close and constant cooperation with  
38 your doctor. Despite diabetes, you can lead an active and healthy life if you eat a balanced diet,  
39 exercise regularly, and take your insulin injections as prescribed by your doctor.

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

43 **70/30 HUMAN INSULIN**

44 **Description**

45 Humulin is synthesized in a special non-disease-producing laboratory strain of *Escherichia coli*  
46 bacteria that has been genetically altered to produce human insulin. Humulin 70/30 is a mixture

47 of 70% Human Insulin Isophane Suspension and 30% Human Insulin Injection (rDNA origin). It  
48 is an intermediate-acting insulin combined with the more rapid onset of action of Regular human  
49 insulin. The duration of activity may last up to 24 hours following injection. The time course of  
50 action of any insulin may vary considerably in different individuals or at different times in the  
51 same individual. As with all insulin preparations, the duration of action of Humulin 70/30 is  
52 dependent on dose, site of injection, blood supply, temperature, and physical activity. Humulin  
53 70/30 is a sterile suspension and is for subcutaneous injection only. It should not be used  
54 intravenously or intramuscularly. The concentration of Humulin 70/30 is 100 units/mL (U-100).

### 55 **Identification**

56 Human insulin from Eli Lilly and Company has the trademark Humulin. Your doctor has  
57 prescribed the type of insulin that he/she believes is best for you.

58 **DO NOT USE ANY OTHER INSULIN EXCEPT ON YOUR DOCTOR'S ADVICE AND**  
59 **DIRECTION.**

60 Always check the carton and the bottle label for the name and letter designation of the insulin  
61 you receive from your pharmacy to make sure it is the same as prescribed by your doctor.

62 Always check the appearance of your bottle of Humulin 70/30 before withdrawing each dose.  
63 Before each injection the Humulin 70/30 bottle must be carefully shaken or rotated several times  
64 to completely mix the insulin. Humulin 70/30 suspension should look uniformly cloudy or milky  
65 after mixing. If not, repeat the above steps until contents are mixed.

66 Do not use Humulin 70/30:

- 67 • if the insulin substance (the white material) remains at the bottom of the bottle after mixing
- 68 or
- 69 • if there are clumps in the insulin after mixing, or
- 70 • if solid white particles stick to the bottom or wall of the bottle, giving a frosted appearance.

71 If you see anything unusual in the appearance of Humulin 70/30 suspension in your bottle or  
72 notice your insulin requirements changing, talk to your doctor.

### 73 **Storage**

74 **Not in-use (unopened):** Humulin 70/30 bottles not in-use should be stored in a refrigerator,  
75 but not in the freezer.

76 **In-use (opened):** The Humulin 70/30 bottle you are currently using can be kept unrefrigerated  
77 as long as it is kept as cool as possible [below 86°F (30°C)] away from heat and light.

78 **Do not use Humulin 70/30 after the expiration date stamped on the label or if it has been**  
79 **frozen.**

## 80 **INSTRUCTIONS FOR INSULIN VIAL USE**

81 **NEVER SHARE NEEDLES AND SYRINGES.**

### 82 **Correct Syringe Type**

83 Doses of insulin are measured in **units**. U-100 insulin contains 100 units/mL (1 mL=1 cc).  
84 With Humulin 70/30, it is important to use a syringe that is marked for U-100 insulin  
85 preparations. Failure to use the proper syringe can lead to a mistake in dosage, causing serious  
86 problems for you, such as a blood glucose level that is too low or too high.

### 87 **Syringe Use**

88 To help avoid contamination and possible infection, follow these instructions exactly.

89 Disposable syringes and needles should be used only once and then discarded by placing the  
90 used needle in a puncture-resistant disposable container. Properly dispose of the puncture-  
91 resistant container as directed by your Health Care Professional.

### 92 **Preparing the Dose**

- 93 1. Wash your hands.
- 94 2. Carefully shake or rotate the bottle of insulin several times to completely mix the insulin.
- 95 3. Inspect the insulin. Humulin 70/30 suspension should look uniformly cloudy or milky. Do  
96 not use Humulin 70/30 if you notice anything unusual in its appearance.

- 97 4. If using a new Humulin 70/30 bottle, flip off the plastic protective cap, but **do not** remove  
98 the stopper. Wipe the top of the bottle with an alcohol swab.
- 99 5. Draw an amount of air into the syringe that is equal to the Humulin 70/30 dose. Put the  
100 needle through rubber top of the Humulin 70/30 bottle and inject the air into the bottle.
- 101 6. Turn the Humulin 70/30 bottle and syringe upside down. Hold the bottle and syringe  
102 firmly in one hand and shake gently.
- 103 7. Making sure the tip of the needle is in the Humulin 70/30 suspension, withdraw the  
104 correct dose of Humulin 70/30 into the syringe.
- 105 8. Before removing the needle from the Humulin 70/30 bottle, check the syringe for air  
106 bubbles. If bubbles are present, hold the syringe straight up and tap its side until the  
107 bubbles float to the top. Push the bubbles out with the plunger and then withdraw the  
108 correct dose.
- 109 9. Remove the needle from the bottle and lay the syringe down so that the needle does not  
110 touch anything.

### 111 **Injection Instructions**

- 112 1. To avoid tissue damage, choose a site for each injection that is at least 1/2 inch from the  
113 previous injection site. The usual sites of injection are abdomen, thighs, and arms.
- 114 2. Cleanse the skin with alcohol where the injection is to be made.
- 115 3. With one hand, stabilize the skin by spreading it or pinching up a large area.
- 116 4. Insert the needle as instructed by your doctor.
- 117 5. Push the plunger in as far as it will go.
- 118 6. Pull the needle out and apply gentle pressure over the injection site for several seconds.  
119 **Do not rub the area.**
- 120 7. Place the used needle in a puncture-resistant disposable container and properly dispose of  
121 the puncture-resistant container as directed by your Health Care Professional.

### 122 **DOSAGE**

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

125 Your usual dose of Humulin 70/30 may be affected by changes in your diet, activity, or work  
126 schedule. Carefully follow your doctor's instructions to allow for these changes. Other things  
127 that may affect your Humulin 70/30 dose are:

### 128 **Illness**

129 Illness, especially with nausea and vomiting, may cause your insulin requirements to change.  
130 Even if you are not eating, you will still require insulin. You and your doctor should establish a  
131 sick day plan for you to use in case of illness. When you are sick, test your blood glucose  
132 frequently. If instructed by your doctor, test your ketones and report the results to your doctor.

### 133 **Pregnancy**

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

### 137 **Medication**

138 Insulin requirements may be increased if you are taking other drugs with blood-glucose-raising  
139 activity, such as oral contraceptives, corticosteroids, or thyroid replacement therapy. Insulin  
140 requirements may be reduced in the presence of drugs that lower blood glucose or affect how  
141 your body responds to insulin, such as oral antidiabetic agents, salicylates (for example, aspirin),  
142 sulfa antibiotics, alcohol, certain antidepressants and some kidney and blood pressure medicines.  
143 Your Health Care Professional may be aware of other medications that may affect your diabetes  
144 control. Therefore, always discuss any medications you are taking with your doctor.

### 145 **Exercise**

146 Exercise may lower your body's need for insulin during and for some time after the physical  
147 activity. Exercise may also speed up the effect of an insulin dose, especially if the exercise

148 involves the area of injection site (for example, the leg should not be used for injection just prior  
149 to running). Discuss with your doctor how you should adjust your insulin regimen to  
150 accommodate exercise.

### 151 **Travel**

152 When traveling across more than 2 time zones, you should talk to your doctor concerning  
153 adjustments in your insulin schedule.

## 154 **COMMON PROBLEMS OF DIABETES**

### 155 **Hypoglycemia (Low Blood Sugar)**

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

- 158 1. **Missing or delaying meals.**
- 159 2. Taking too much insulin.
- 160 3. Exercising or working more than usual.
- 161 4. An infection or illness associated with diarrhea or vomiting.
- 162 5. A change in the body's need for insulin.
- 163 6. Diseases of the adrenal, pituitary, or thyroid gland, or progression of kidney or liver  
164 disease.
- 165 7. Interactions with certain drugs, such as oral antidiabetic agents, salicylates (for example,  
166 aspirin), sulfa antibiotics, certain antidepressants and some kidney and blood pressure  
167 medicines.
- 168 8. Consumption of alcoholic beverages.

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

- |  |                       |
|--|-----------------------|
| 170 • sweating                                     | • drowsiness          |
| 171 • dizziness                                    | • sleep disturbances  |
| 172 • palpitation                                  | • anxiety             |
| 173 • tremor                                       | • blurred vision      |
| 174 • hunger                                       | • slurred speech      |
| 175 • restlessness                                 | • depressed mood      |
| 176 • tingling in the hands, feet, lips, or tongue | • irritability        |
| 177 • lightheadedness                              | • abnormal behavior   |
| 178 • inability to concentrate                     | • unsteady movement   |
| 179 • headache                                     | • personality changes |

180 Signs of severe hypoglycemia can include:

- |                       |            |
|-----------------------|------------|
| 181 • disorientation  | • seizures |
| 182 • unconsciousness | • death    |

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

184 Early warning symptoms of hypoglycemia may be different or less pronounced under certain  
185 conditions, such as long duration of diabetes, diabetic nerve disease, use of medications such as  
186 beta-blockers, changing insulin preparations, or intensified control (3 or more insulin injections  
187 per day) of diabetes.

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

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

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

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

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

### 209 **Hyperglycemia (High Blood Sugar) and Diabetic Ketoacidosis (DKA)**

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

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

215 In patients with type 1 or insulin-dependent diabetes, prolonged hyperglycemia can result in  
216 DKA (a life-threatening emergency). The first symptoms of DKA usually come on gradually,  
217 over a period of hours or days, and include a drowsy feeling, flushed face, thirst, loss of appetite,  
218 and fruity odor on the breath. With DKA, blood and urine tests show large amounts of glucose  
219 and ketones. Heavy breathing and a rapid pulse are more severe symptoms. If uncorrected,  
220 prolonged hyperglycemia or DKA can lead to nausea, vomiting, stomach pain, dehydration, loss  
221 of consciousness, or death. Therefore, it is important that you obtain medical assistance  
222 immediately.

### 223 **Lipodystrophy**

224 Rarely, administration of insulin subcutaneously can result in lipoatrophy (seen as an apparent  
225 depression of the skin) or lipohypertrophy (seen as a raised area of the skin). If you notice either  
226 of these conditions, talk to your doctor. A change in your injection technique may help alleviate  
227 the problem.

### 228 **Allergy**

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

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

## 238 **ADDITIONAL INFORMATION**

239 Information about diabetes may be obtained from your diabetes educator.

240 Additional information about diabetes and Humulin can be obtained by calling The Lilly  
241 Answers Center at 1-800-LillyRx (1-800-545-5979) or by visiting [www.LillyDiabetes.com](http://www.LillyDiabetes.com).

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

245  
246 **for Wal-Mart Stores, Inc.**  
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