HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use HUMULIN 70/30 safely and effectively. See full prescribing information for HUMULIN 70/30.

HUMULIN 70/30 (insulin isophane human and insulin human) injectable suspension, for subcutaneous use

Initial U.S. Approval: 1989

---------- INDICATIONS AND USAGE ----------

HUMULIN® 70/30 is a mixture of insulin isophane human, an intermediate-acting human insulin, and insulin human, a short-acting insulin human, indicated to improve glycemic control in adults with diabetes mellitus. (1)

----------DOSAGE AND ADMINISTRATION----------

- Only administer subcutaneously (in abdominal wall, thigh, upper arm, or buttocks). (2.1)
- Rotate injection sites to reduce risk of lipodystrophy and localized cutaneous amyloidosis. (2.1)
- Individualize and adjust dosage based on metabolic needs, blood glucose monitoring results and glycemic control goal. (2.2)
- See Full Prescribing Information for dosage adjustments due to drug interactions and patients with renal and hepatic impairment. (2.2)
- Administer approximately 30-45 minutes before a meal. (2.2)

----------DOSAGE FORMS AND STRENGTHS----------

Injectable suspension 100 units/mL (U-100) available as:

- 10 mL multiple-dose vial (3)
- 3 mL single-patient-use HUMULIN® 70/30 KwikPen® prefilled pen (3)

---------- CONTRAINDICATIONS ----------

- During episodes of hypoglycemia. (4)
- In patients with hypersensitivity to HUMULIN 70/30 or any of its excipients. (4)

----------WARNINGS AND PRECAUTIONS----------

- Never share a HUMULIN 70/30 KwikPen or syringe between patients, even if the needle is changed. (5.1)
- *Hyperglycemia or Hypoglycemia with Changes in Insulin Regimen*: Make changes to a patient's insulin regimen (e.g., insulin strength, manufacturer, type, injection site or method of administration) under close medical supervision with increased frequency of blood glucose monitoring. (5.2)
- *Hypoglycemia*: May be life-threatening. Monitor blood glucose and increase monitoring frequency with changes to insulin dosage, use of glucose lowering medications, meal pattern, physical activity; in patients with renal or hepatic impairment; and in patients with hypoglycemia unawareness. (5.3, 7, 8.6, 8.7)
- *Hypoglycemia Due to Medication Errors:* Accidental mix-ups between insulin products can occur. Instruct patients to check insulin labels before injection. (5.4)
- *Hypersensitivity Reactions*: May be life-threatening. Discontinue HUMULIN 70/30, monitor and treat if indicated. (5.5)
- *Hypokalemia*: May be life-threatening. Monitor potassium levels in patients at risk of hypokalemia and treat if indicated. (5.6)
- *Fluid Retention and Heart Failure with Concomitant Use of Thiazolidinediones (TZDs)*: Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation if heart failure occurs. (5.7)

----------ADVERSE REACTIONS----------

Adverse reactions observed with insulin therapy include hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, pruritus, rash, weight gain, and edema. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Eli Lilly and Company at 1-800-LillyRx (1-800-545-5979) or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

---------- DRUG INTERACTIONS ----------

- *Drugs that Affect Glucose Metabolism:* Adjustment of insulin dosage may be needed. (7)
- *Antiadrenergic Drugs (e.g., beta-blockers, clonidine, guanethidine, and reserpine):* Signs and symptoms of hypoglycemia may be reduced or absent. (5.3, 7)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

Revised: 12/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

HUMULIN 70/30 is a fixed ratio insulin formulation indicated to improve glycemic control in adults with diabetes mellitus.

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

Inspect HUMULIN 70/30 visually before use. It should not contain particulate matter and should appear uniformly cloudy after mixing. Do not use HUMULIN 70/30 if particulate matter is seen.

- Administer HUMULIN 70/30 subcutaneously into the abdominal wall, thigh, upper arm, or buttocks. Rotate injection sites within the same region from one injection to the next to reduce the risk of lipodystrophy and localized cutaneous amyloidosis. Do not inject into areas of lipodystrophy or localized cutaneous amyloidosis *[see Warnings and Precautions (5.2) and Adverse Reactions (6)]*.
- The HUMULIN 70/30 KwikPen dials in 1 unit increments.
- Use HUMULIN 70/30 KwikPen with caution in patients with visual impairment that may rely on audible clicks to dial their dose.
- Do not administer HUMULIN 70/30 intravenously and do not use in an insulin infusion pump.
- Do not mix HUMULIN 70/30 with any other insulins or diluents.

2.2 Dosage Information

- Inject HUMULIN 70/30 subcutaneously approximately 30-45 minutes before a meal.
- The proportion of rapid acting and long acting insulin is fixed in a premixed insulin such as HUMULIN 70/30. Independent adjustment of the basal or prandial dose is not possible when using a premixed insulin.
- Individualize and adjust the dosage of HUMULIN 70/30 based on the individual's metabolic needs, blood glucose monitoring results and glycemic control goal. Dosage adjustments may be needed with changes in physical activity, changes in meal patterns (i.e., macronutrient content or timing of food intake), changes in renal or hepatic function or during acute illness *[see Warnings and Precautions (5.2, 5.3), and Use in Specific Populations (8.6, 8.7)]*.
- During changes to a patient's insulin regimen, increase the frequency of blood glucose monitoring *[see Warnings and Precautions (5.2)]*.
- HUMULIN 70/30 dose requirements may change with changes in level of physical activity, meal patterns (i.e., macronutrient content or timing of food intake), during major illness, or with some coadministered drugs *[see Warnings and Precautions (5.3), Drug Interactions (7), and Use in Specific Populations (8.6, 8.7)]*.

3 DOSAGE FORMS AND STRENGTHS

Injectable suspension: 70% insulin isophane human and 30% insulin human, 100 units/mL (U-100), white and cloudy suspension available as:

- 10 mL multiple-dose vial
- 3 mL single-patient-use HUMULIN 70/30 KwikPen prefilled pen

4 CONTRAINDICATIONS

HUMULIN 70/30 is contraindicated:

- During episodes of hypoglycemia *[see Warnings and Precautions (5.3)],* and
- In patients who have had hypersensitivity reactions to HUMULIN 70/30 or any of its excipients *[see Warnings and Precautions (5.5)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Never Share a HUMULIN 70/30 KwikPen or Syringe Between Patients

HUMULIN 70/30 KwikPens must never be shared between patients, even if the needle is changed. Patients using HUMULIN 70/30 vials must never share needles or syringes with another person. Sharing poses a risk for transmission of blood-borne pathogens.

5.2 Hyperglycemia or Hypoglycemia with Changes in Insulin Regimen

Changes in an insulin regimen (e.g., insulin strength, manufacturer, type, injection site or method of administration) may affect glycemic control and predispose to hypoglycemia *[see Warnings and Precautions (5.3)]* or hyperglycemia. Repeated insulin injections into areas of lipodystrophy or localized cutaneous amyloidosis have been reported to result in hyperglycemia; and a sudden change in the injection site (to an unaffected area) has been reported to result in hypoglycemia *[see Adverse Reactions (6)]*.

Make any changes to a patient's insulin regimen under close medical supervision with increased frequency of blood glucose monitoring. Advise patients who have repeatedly injected into areas of lipodystrophy or localized cutaneous amyloidosis to change the injection site to unaffected areas and closely monitor for hypoglycemia. For patients with type 2 diabetes, dosage adjustments of concomitant antidiabetic products may be needed.

5.3 Hypoglycemia

Hypoglycemia is the most common adverse reaction associated with insulins, including HUMULIN 70/30. Severe hypoglycemia can cause seizures, may be life-threatening or cause death. Hypoglycemia can impair concentration ability

and reaction time; this may place the patient and others at risk in situations where these abilities are important (e.g., driving or operating other machinery).

Hypoglycemia can happen suddenly and symptoms may differ in each patient and change over time in the same patient. Symptomatic awareness of hypoglycemia may be less pronounced in patients with longstanding diabetes, in patients with diabetic neuropathy, in patients using medications that block the sympathetic nervous system (e.g., beta-blockers) *[see Drug Interactions (7)]*, or in patients who experience recurrent hypoglycemia.

Risk Factors for Hypoglycemia

The risk of hypoglycemia after an injection is related to the duration of action of the insulin and, in general, is highest when the glucose lowering effect of the insulin is maximal. As with all insulins, the glucose lowering effect time course of HUMULIN 70/30 may vary in different individuals or at different times in the same individual and depends on many conditions, including the area of injection as well as the injection site blood supply and temperature *[see Clinical Pharmacology (12.2)]*.

Other factors which may increase the risk of hypoglycemia include changes in meal pattern (e.g., macronutrient content or timing of meals), changes in level of physical activity, or changes to concomitant drugs *[see Drug Interactions (7)]*. Patients with renal or hepatic impairment may be at higher risk of hypoglycemia *[see Use in Specific Populations (8.6, 8.7)]*.

Risk Mitigation Strategies for Hypoglycemia

Patients and caregivers must be educated to recognize and manage hypoglycemia. Self-monitoring of blood glucose plays an essential role in the prevention and management of hypoglycemia. In patients at higher risk for hypoglycemia and patients who have reduced symptomatic awareness of hypoglycemia, increased frequency of blood glucose monitoring is recommended.

5.4 Hypoglycemia Due to Medication Errors

Accidental mix-ups between insulin products have been reported. To avoid medication errors between HUMULIN 70/30 and other insulins, instruct patients to always check the insulin label before each injection.

5.5 Hypersensitivity Reactions

Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulins, including HUMULIN 70/30. If hypersensitivity reactions occur, discontinue HUMULIN 70/30; treat per standard of care and monitor until symptoms and signs resolve *[see Adverse Reactions (6)]*. HUMULIN 70/30 is contraindicated in patients who have had hypersensitivity reactions to HUMULIN 70/30 or any of its excipients.

5.6 Hypokalemia

All insulins, including HUMULIN 70/30, cause a shift in potassium from the extracellular to intracellular space, possibly leading to hypokalemia. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk for hypokalemia if indicated (e.g., patients using potassium-lowering medications, patients taking medications sensitive to serum potassium concentrations).

5.7 Fluid Retention and Heart Failure with Concomitant Use of PPAR-gamma Agonists

Thiazolidinediones (TZDs), which are peroxisome proliferator-activated receptor (PPAR)-gamma agonists, can cause dose-related fluid retention, when used in combination with insulin. Fluid retention may lead to or exacerbate heart failure. Patients treated with insulin, including HUMULIN 70/30, and a PPAR-gamma agonist should be observed for signs and symptoms of heart failure. If heart failure develops, it should be managed according to current standards of care, and discontinuation or dose reduction of the PPAR-gamma agonist must be considered.

6 ADVERSE REACTIONS

The following adverse reactions are discussed elsewhere in the labeling:

- Hypoglycemia *[see Warnings and Precautions (5.3)]*.
- Hypoglycemia Due to Medication Errors *[see Warnings and Precautions (5.4)]*.
- Hypersensitivity Reactions *[see Warnings and Precautions (5.5)]*.
- Hypokalemia *[see Warnings and Precautions (5.6)]*.

The following additional adverse reactions have been identified during post-approval use of HUMULIN 70/30. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or to establish a causal relationship to drug exposure.

Allergic Reactions

Some patients taking HUMULIN 70/30 have experienced erythema, local edema, and pruritus at the site of injection. These conditions were usually self-limiting. Severe cases of generalized allergy (anaphylaxis) have been reported *[see Warnings and Precautions (5.5)]*.

Peripheral Edema

Some patients taking HUMULIN 70/30 have experienced sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy.

Lipodystrophy

Administration of insulin subcutaneously, including HUMULIN 70/30, has resulted in lipoatrophy (depression in the skin) or lipohypertrophy (enlargement or thickening of tissue) *[see Dosage and Administration (2.1)]* in some patients.

Localized Cutaneous Amyloidosis

Localized cutaneous amyloidosis at the injection site has occurred. Hyperglycemia has been reported with repeated insulin injections into areas of localized cutaneous amyloidosis; hypoglycemia has been reported with a sudden change to an unaffected injection site.

Weight gain

Weight gain has occurred with insulins, including HUMULIN 70/30, and has been attributed to the anabolic effects of insulin and the decrease in glycosuria.

Immunogenicity

Development of antibodies that react with human insulin have been observed with all insulins, including HUMULIN 70/30.

7 DRUG INTERACTIONS

Table 1: Clinically Significant Drug Interactions with HUMULIN 70/30

Drugs that May Increase the Risk of Hypoglycemia	
Drugs:	Antidiabetic agents, ACE inhibitors, angiotensin II receptor blocking agents, disopyramide, fibrates, fluoxetine, monoamine oxidase inhibitors, pentoxifylline, pramlintide, salicylates, somatostatin analog (e.g., octreotide), and sulfonamide antibiotics
Intervention:	Dose adjustment and increased frequency of glucose monitoring may be required when HUMULIN 70/30 is co-administered with these drugs.
Drugs that May Decrease the Blood Glucose Lowering Effect of HUMULIN 70/30	
Drugs:	Atypical antipsychotics (e.g., olanzapine and clozapine), corticosteroids, danazol, diuretics, estrogens, glucagon, isoniazid, niacin, oral contraceptives, phenothiazines, progestogens (e.g., in oral contraceptives), protease inhibitors, somatropin, sympathomimetic agents (e.g., albuterol, epinephrine, terbutaline), and thyroid hormones.
Intervention:	Dose adjustment and increased frequency of glucose monitoring may be required when HUMULIN 70/30 is co-administered with these drugs.
Drugs that May Increase or Decrease the Blood Glucose Lowering Effect of HUMULIN 70/30	
Drugs:	Alcohol, beta-blockers, clonidine, and lithium salts. Pentamidine may cause hypoglycemia, which may sometimes be followed by hyperglycemia.
Intervention:	Dose adjustment and increased frequency of glucose monitoring may be required when HUMULIN 70/30 is co-administered with these drugs.
Drugs that May Blunt Signs and Symptoms of Hypoglycemia	
Drugs:	Beta-blockers, clonidine, guanethidine, and reserpine
Intervention:	Increased frequency of glucose monitoring may be required when HUMULIN 70/30 is co-administered with these drugs.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available data from published studies over decades have not established an association with human insulin use during pregnancy and major birth defects, miscarriage, or adverse maternal or fetal outcomes (*see* Data). There are risks to the mother and fetus associated with poorly controlled diabetes in pregnancy (*see* Clinical Considerations). Animal reproduction studies were not performed.

The estimated background risk of major birth defects is 6-10% in women with pre-gestational diabetes with a HbA1c >7% and has been reported to be as high as 20-25% in women with a HbA1c >10%. The estimated background risk of miscarriage for the indicated population is unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2-4% and 15-20%, respectively.

Clinical Considerations

Disease-associated maternal and/or embryo/fetal risk

Poorly controlled diabetes in pregnancy increases the maternal risk for diabetic ketoacidosis, pre-eclampsia, spontaneous abortions, preterm delivery, and delivery complications. Poorly controlled diabetes increases the fetal risk for major birth defects, stillbirth, and macrosomia-related morbidity.

Data

Human Data

While available studies cannot definitively establish the absence of risk, published data from retrospective studies, open-label, randomized, parallel studies and meta-analyses over decades have not established an association with human insulin use during pregnancy and major birth defects, miscarriage, or adverse maternal or fetal outcomes. All available studies have methodological limitations, including lack of blinding, unclear methods or randomization, and small sample size.

8.2 Lactation

Risk Summary

Available data from published literature suggests that exogenous human insulin products, including HUMULIN 70/30, are transferred into human milk. There are no adverse reactions reported in breastfed infants in the literature. There are no data on the effects of exogenous human insulin products, including HUMULIN 70/30 on milk production. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for HUMULIN 70/30 and any potential adverse effects on the breastfed child from HUMULIN 70/30 or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of HUMULIN 70/30 in pediatric patients have not been established.

8.5 Geriatric Use

The effect of age on the pharmacokinetics and pharmacodynamics of HUMULIN 70/30 has not been studied *[see Clinical Pharmacology (12.3)]*. Patients with advanced age using any insulin, including HUMULIN 70/30, may be at increased risk of hypoglycemia due to co-morbid disease and polypharmacy *[see Warnings and Precautions (5.3)]*.

8.6 Renal Impairment

The effect of renal impairment on the pharmacokinetics and pharmacodynamics of HUMULIN 70/30 has not been studied *[see Clinical Pharmacology (12.3)]*. Patients with renal impairment are at increased risk of hypoglycemia and may require more frequent HUMULIN 70/30 dose adjustment and more frequent blood glucose monitoring.

8.7 Hepatic Impairment

The effect of hepatic impairment on the pharmacokinetics and pharmacodynamics of HUMULIN 70/30 has not been studied *[see Clinical Pharmacology (12.3)]*. Patients with hepatic impairment are at increased risk of hypoglycemia and may require more frequent HUMULIN 70/30 dose adjustment and more frequent blood glucose monitoring.

10 OVERDOSAGE

Excess insulin administration may cause hypoglycemia and hypokalemia *[see Warnings and Precautions (5.3, 5.6)]*. Mild episodes of hypoglycemia can be treated with oral glucose. Adjustments in drug dosage, meal patterns, or physical activity level may be needed. More severe episodes with coma, seizure, or neurologic impairment may be treated with a glucagon product for emergency use or concentrated intravenous glucose. Sustained carbohydrate intake and observation may be necessary because hypoglycemia may recur after apparent clinical recovery. Hypokalemia must be corrected appropriately.

11 DESCRIPTION

Insulin human is produced by recombinant DNA technology utilizing a non-pathogenic laboratory strain of Escherichia coli. The amino acid sequence of insulin human is identical to human insulin and has the empirical formula $C_{257}H_{383}N_{65}O_{77}S_6$ with a molecular weight of 5.808 kDa.

HUMULIN 70/30 (insulin isophane human and insulin human) injectable suspension is a mixture of 70% insulin isophane human suspension, an intermediate-acting insulin, and 30% insulin human injection, a short-acting insulin. HUMULIN 70/30 is a suspension of crystals produced from combining insulin human and protamine sulfate under appropriate conditions for crystal formation and mixing with insulin human injection.

HUMULIN 70/30 is a sterile, white and cloudy suspension that contains insulin isophane human suspension (NPH) and insulin human injection (regular) for subcutaneous use. Each milliliter of HUMULIN 70/30 contains 100 units of insulin human, dibasic sodium phosphate (3.78 mg), glycerin (16 mg), metacresol (1.6 mg), phenol (0.65 mg), protamine sulfate (0.24 mg), zinc oxide content adjusted to provide 0.025 mg zinc ion, and Water for Injection. The pH is 7.0 to 7.8. Sodium hydroxide and/or hydrochloric acid may be added during manufacture to adjust the pH.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

HUMULIN 70/30 lowers blood glucose by stimulating peripheral glucose uptake by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulins inhibit lipolysis and proteolysis, and enhance protein synthesis.

12.2 Pharmacodynamics

HUMULIN 70/30 combines an intermediate-acting insulin with the more rapid onset of action of regular human insulin. In healthy males (n=18) given HUMULIN 70/30 (0.3 unit/kg) subcutaneously, the pharmacologic effect began at approximately 50 minutes (range: 30 to 90 minutes) (*see* Figure 1). The effect was maximal at approximately 3.5 hours (range: 1.5 to 6.5 hours) and the mean duration of action was relatively long (approximately 23 hours; range: 18-24 hours).

Figure 1 should be considered only as a representative example since the time course of action of insulin may vary in different individuals or within the same individual. The rate of insulin absorption and consequently the onset of activity is known to be affected by the site of injection, physical activity level, and other variables *[see Warnings and Precautions (5.3)]*.

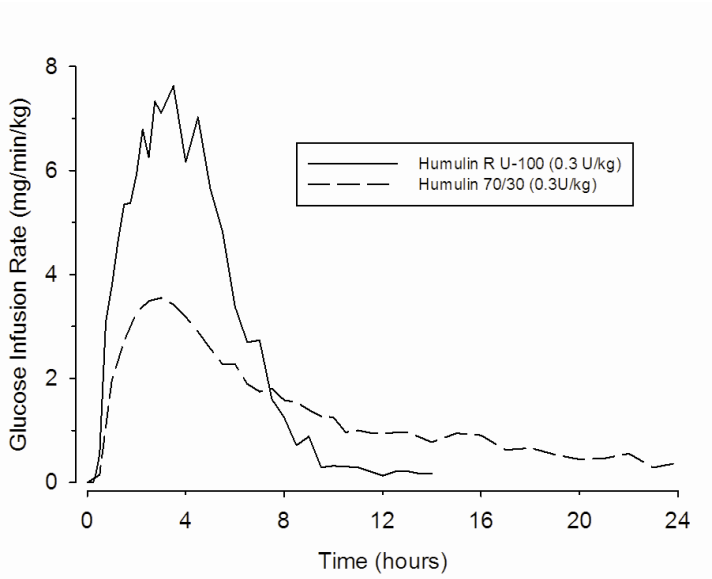

Figure 1: Mean Insulin Activity Versus Time Profiles After Subcutaneous Injection of HUMULIN 70/30 or HUMULIN® R U-100 (0.3 unit/kg) in Healthy Subjects.

12.3 Pharmacokinetics

Absorption — In healthy male subjects given HUMULIN 70/30 (0.3 unit/kg) subcutaneously, the mean peak serum concentration occurred at 2.2 hours (range: 1 to 5 hours) after dosing.

Metabolism — The uptake and degradation of insulin occurs predominantly in liver, kidney, muscle, and adipocytes, with the liver being the major organ involved in the clearance of insulin.

Elimination — Because of the absorption-rate limited kinetics of insulin mixtures, a true half-life cannot be accurately estimated from the terminal slope of the concentration versus time curve.

Specific Populations

The effects of age, gender, race, obesity, pregnancy, or smoking on the pharmacokinetics of HUMULIN 70/30 have not been studied.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Carcinogenicity and fertility studies were not performed in animals. Biosynthetic human insulin was not genotoxic in the *in vivo* sister chromatid exchange assay and the *in vitro* gradient plate and unscheduled DNA synthesis assays.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

HUMULIN 70/30 (insulin isophane human and insulin human) injectable suspension is 70% insulin isophane human and 30% insulin human, 100 units/mL (U-100), a white and cloudy suspension available as:

10 mL multiple-dose vial	NDC 0002-8715-01 (HI-710)
5 x 3 mL single-patient-use HUMULIN 70/30 KwikPen	NDC 0002-8803-59 (HP-8803)

Each prefilled HUMULIN 70/30 KwikPen is for use by a single patient. HUMULIN 70/30 KwikPens must never be shared between patients, even if the needle is changed. Patients using HUMULIN 70/30 vials must never share needles or syringes with another person.

The HUMULIN 70/30 KwikPen dials in 1 unit increments.

16.2 Storage and Handling

Dispense in the original sealed carton with the enclosed Instructions for Use.

Protect from heat and light. Do not freeze. Do not use if it has been frozen. See Table 2 below for storage conditions.

Table 2: Storage Conditions for HUMULIN 70/30 Vials and Pens

	Not In-use (Unopened)		In-use (Opened)	
	Room Temperature (up to 86°F [30°C])	**Refrigerated (36° to 46°F [2° to 8°C])**	**Room Temperature (up to 86°F [30°C])**	**Refrigerated (36° to 46°F [2° to 8°C])**
10 mL multiple-dose vial[a]	31 days	Until expiration date	31 days	31 days
3 mL single-patient-use HUMULIN 70/30 KwikPen[b]	10 days	Until expiration date	10 days	**Do not refrigerate.**

[a] When stored at room temperature, HUMULIN 70/30 vial can only be used for a total of 31 days including both not in-use (unopened) and in-use (opened) storage time.

[b] When stored at room temperature, HUMULIN 70/30 KwikPen can only be used for a total of 10 days including both not in-use (unopened) and in-use (opened) storage time.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Never Share a HUMULIN 70/30 KwikPen or Syringe Between Patients

Advise patients that they must never share a HUMULIN 70/30 KwikPen with another person, even if the needle is changed. Advise patients using HUMULIN 70/30 vials not to share needles or syringes with another person. Sharing poses a risk for transmission of blood-borne pathogens *[see Warnings and Precautions (5.1)]*.

Hyperglycemia or Hypoglycemia

Instruct patients on self-management procedures including glucose monitoring, proper injection technique, and management of hypoglycemia and hyperglycemia especially at initiation of HUMULIN 70/30 therapy. Instruct patients on handling of special situations such as intercurrent conditions (illness, stress, or emotional disturbances), an inadequate or skipped insulin dose, inadvertent administration of an increased insulin dose, inadequate food intake, and skipped meals. Instruct patients on the management of hypoglycemia.

Inform patients that their ability to concentrate and react may be impaired as a result of hypoglycemia. Advise patients who have frequent hypoglycemia or reduced or absent warning signs of hypoglycemia to use caution when driving or operating machinery *[see Warnings and Precautions (5.3)]*.

Advise patients that changes in insulin regimen can predispose to hyperglycemia or hypoglycemia and that changes in insulin regimen should be made under close medical supervision *[see Warnings and Precautions (5.2)]*.

Inform patients that accidental mix-ups between insulin products have been reported. Instruct patients to always carefully check that they are administering the correct insulin (e.g., by checking the insulin label before each injection) to avoid medication errors between HUMULIN 70/30 and other insulins.

Hypersensitivity Reactions

Advise patients that hypersensitivity reactions have occurred with HUMULIN 70/30. Inform patients on the symptoms of hypersensitivity reactions *[see Warnings and Precautions (5.5)]*.

Literature revised December 2025

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