NOVOLIN 70/30- human insulin injection, suspension
Novo Nordisk Pharmaceutical Industries, LP

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use NOVOLIN 70/30 safely and effectively. See full prescribing information for NOVOLIN 70/30.
NOVOLIN® 70/30 (insulin isophane human and insulin human) injectable suspension, for subcutaneous use
Initial U.S. Approval: 1991

INDICATIONS AND USAGE

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

DOSAGE AND ADMINISTRATION

- See Full Prescribing Information for important administration instructions. (2.1)
- Inject subcutaneously in abdominal wall, thigh, upper arm, or buttocks and 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)
- Inject NOVOLIN 70/30 subcutaneously approximately 30 minutes prior to start of meal. (2.2)
- NOVOLIN 70/30 is typically dosed twice daily (with each dose intended to cover 2 meals or a meal and a snack). (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 NOVOLIN 70/30 FlexPen prefilled pen (3)

CONTRAINDICATIONS

- During episodes of hypoglycemia (4)
- Hypersensitivity to NOVOLIN 70/30 or any of its excipients (4)

WARNINGS AND PRECAUTIONS

- Never share a NOVOLIN 70/30 FlexPen 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. Increase frequency of blood glucose monitoring with changes to: insulin dosage, co-administered glucose lowering medications, meal pattern, physical activity; in patients with renal or hepatic impairment; and in patients with hypoglycemia unawareness. (5.3)
- *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:* Severe, life-threatening, generalized allergy, including anaphylaxis, can occur. Discontinue NOVOLIN 70/30, monitor, and treat if indicated. (5.5)
- *Hypokalemia:* May be life-threatening. Monitor potassium levels in patients at risk for 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 NOVOLIN 70/30 include hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, weight gain and edema. (6)
To report SUSPECTED ADVERSE REACTIONS, contact Novo Nordisk Inc. at 1-800-727-6500 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: 11/2022

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

NOVOLIN 70/30 is indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus.

Limitations of Use:

In NOVOLIN 70/30, the proportions of short-acting and intermediate-acting insulins are fixed and do not allow for basal versus prandial dose adjustments.

2 DOSAGE AND ADMINISTRATION

2.1 Important Administration Instructions

- Always check insulin labels before administration *[see Warnings and Precautions (5.4)].*
- NOVOLIN 70/30 is a suspension that must be resuspended immediately before use. Resuspension is easier when the insulin has reached room temperature.
- To resuspend vial, roll the vial gently in your hands in a horizontal position 10 times until the suspension appears uniformly white and cloudy. Inject immediately.
- To resuspend FlexPen, gently move the pen up and down 20 times so the glass ball moves from one end of the cartridge to the other until the suspension appears uniformly white and cloudy. Inject immediately.
- Inspect NOVOLIN 70/30 visually before use. Do not use NOVOLIN 70/30 if discoloration or particulate matter is seen.
- Administer NOVOLIN 70/30 by subcutaneous injection in the abdominal wall, thigh, upper arm, or buttocks.
- Rotate the injection site 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), Adverse Reactions (6)]*.
- During changes to a patient's insulin regimen, increase the frequency of blood glucose monitoring *[see Warnings and Precautions (5.2)]*.
- Do not administer NOVOLIN 70/30 intravenously and do not use in an insulin infusion pump.
- Do not mix NOVOLIN 70/30 with any other insulins or diluents.

2.2 Dosage Information

- Individualize and adjust the dosage of NOVOLIN 70/30 based on the individual's metabolic needs, blood glucose monitoring results and glycemic control goal.
- Inject NOVOLIN 70/30 subcutaneously approximately 30 minutes before a meal.
- NOVOLIN 70/30 is typically dosed twice daily (with each dose intended to cover 2 meals or a meal and a snack).
- 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)].*
- Dosage adjustment may be needed when switching from another insulin to NOVOLIN 70/30 *[see Warnings and Precautions (5.2)].*

2.3 Dosage Adjustment due to Drug Interactions

- Dosage adjustment may be needed when NOVOLIN 70/30 is co-administered with certain drugs *[see Drug Interactions (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 NOVOLIN 70/30 FlexPen prefilled pen

4 CONTRAINDICATIONS

NOVOLIN 70/30 is contraindicated:

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

5 WARNINGS AND PRECAUTIONS

5.1 Never Share a NOVOLIN 70/30 FlexPen or Syringe between Patients

NOVOLIN 70/30 FlexPen must never be shared between patients, even if the needle is changed. Patients using NOVOLIN 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 anti-diabetic products may be needed.

5.3 Hypoglycemia

Hypoglycemia is the most common adverse reaction of all insulins, including NOVOLIN 70/30. Severe hypoglycemia can cause seizures, may lead to unconsciousness 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 time course of glucose lowering effect of NOVOLIN 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. 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 NOVOLIN 70/30 and other insulin products have been reported. To avoid medication errors between NOVOLIN 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 NOVOLIN 70/30. Generalized allergy to insulin may manifest as a whole body rash (including pruritus), dyspnea, wheezing, hypotension, tachycardia, or diaphoresis. If hypersensitivity reactions occur, discontinue NOVOLIN 70/30; treat per standard of care and monitor until symptoms and signs resolve. NOVOLIN 70/30 is contraindicated in patients who have had hypersensitivity reactions to NOVOLIN 70/30 or its excipients.

5.6 Hypokalemia

All insulins, including NOVOLIN 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 concentration).

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 NOVOLIN 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 also discussed elsewhere in the labeling:

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

Adverse Reactions from Clinical Studies or Postmarketing Reports

The following additional adverse reactions have been identified during clinical studies or from postmarketing reports with use of NOVOLIN 70/30. Because some of 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.

Adverse reactions associated with insulin initiation and glucose control intensification

Intensification or rapid improvement in glucose control has been associated with a transitory, reversible ophthalmologic refraction disorder, worsening of diabetic retinopathy, and acute painful peripheral neuropathy. Over the long-term, improved glycemic control decreases the risk of diabetic retinopathy and neuropathy.

Hypersensitivity reactions

Severe, life-threatening, generalized allergy, including anaphylaxis.

Hypoglycemia

Hypoglycemia is the most commonly observed adverse reaction in NOVOLIN 70/30.

Hypokalemia

NOVOLIN 70/30 can cause a shift in potassium from the extracellular to intracellular

space, possibly leading to hypokalemia.

Injection site reactions

NOVOLIN 70/30 can cause local injection site reactions including redness, swelling, or itching at the site of injection. These reactions usually resolve in a few days to a few weeks, but in some occasions, may require discontinuation. Localized reactions and generalized myalgias have been reported with the use of metacresol, which is an excipient in NOVOLIN 70/30.

Lipodystrophy

Administration of insulin subcutaneously, including NOVOLIN 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.

Medication Errors

Medication errors in which other insulins have been accidentally substituted for NOVOLIN 70/30 have been identified during postapproval use.

Peripheral edema

Insulins, including NOVOLIN 70/30, may cause sodium retention and edema, particularly if previously poor metabolic control is improved by intensified insulin therapy.

Weight gain

Weight gain can occur with insulins, including NOVOLIN 70/30, and has been attributed to the anabolic effects of insulin and the decrease in glucosuria.

Immunogenicity

As with all therapeutic proteins, insulin administration may cause anti-insulin antibodies to form. The incidence of antibody formation with NOVOLIN 70/30 is unknown.

7 DRUG INTERACTIONS

Table 1: Clinically Significant Drug Interactions with NOVOLIN 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 NOVOLIN 70/30 is co-administered with these drugs.
Drugs that May Decrease the Blood Glucose Lowering Effect of NOVOLIN 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 NOVOLIN 70/30 is co-administered with these

	drugs.
Drugs that May Increase or Decrease the Blood Glucose Lowering Effect of NOVOLIN 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 NOVOLIN 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 NOVOLIN 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 HbA_{1c} >7 and has been reported to be as high as 20-25% in women with a HbA_{1c} >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 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 of randomization, and small sample size.

8.2 Lactation

Risk Summary

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

adverse effects on the breastfed infant from NOVOLIN 70/30, or from the underlying maternal condition.

8.4 Pediatric Use

NOVOLIN 70/30 is indicated to improve glycemic control in pediatric patients with diabetes mellitus.

The dosage of NOVOLIN 70/30 must be individualized in pediatric patients based on metabolic needs and frequent monitoring of blood glucose to reduce the risk of hypoglycemia *[see Dosage and Administration (2.2) and Warnings and Precautions (5.3)]*.

8.5 Geriatric Use

The effect of age on the pharmacokinetics and pharmacodynamics of NOVOLIN 70/30 has not been studied. Elderly patients using insulin, including NOVOLIN 70/30, may be at increased risk of hypoglycemia due to co-morbid disease *[see Warnings and Precautions (5.3)]*.

8.6 Renal Impairment

The effect of renal impairment on the pharmacokinetics and pharmacodynamics of NOVOLIN 70/30 has not been studied. Patients with renal impairment are at increased risk of hypoglycemia and may require more frequent NOVOLIN 70/30 dose adjustment and more frequent blood glucose monitoring *[see Warnings and Precautions (5.3)]*.

8.7 Hepatic Impairment

The effect of hepatic impairment on the pharmacokinetics and pharmacodynamics of NOVOLIN 70/30 has not been studied. Patients with hepatic impairment are at increased risk of hypoglycemia and may require more frequent NOVOLIN 70/30 dose adjustment and more frequent blood glucose monitoring *[see Warnings and Precautions (5.3)]*.

10 OVERDOSAGE

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

11 DESCRIPTION

Insulin human is produced by recombinant DNA technology, utilizing *Saccharomyces cerevisiae* (baker's yeast) as the production organism. The amino acid sequence of insulin human is identical to human insulin and has the empirical formula $C_{257}H_{383}N_{65}O_{77}S_6$ and a molecular weight of 5808 Da.

NOVOLIN 70/30 (insulin isophane human and insulin human) injectable suspension is a mixture of 70% of insulin isophane human, an intermediate-acting insulin, and 30% of insulin human, a short-acting insulin. NOVOLIN 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.

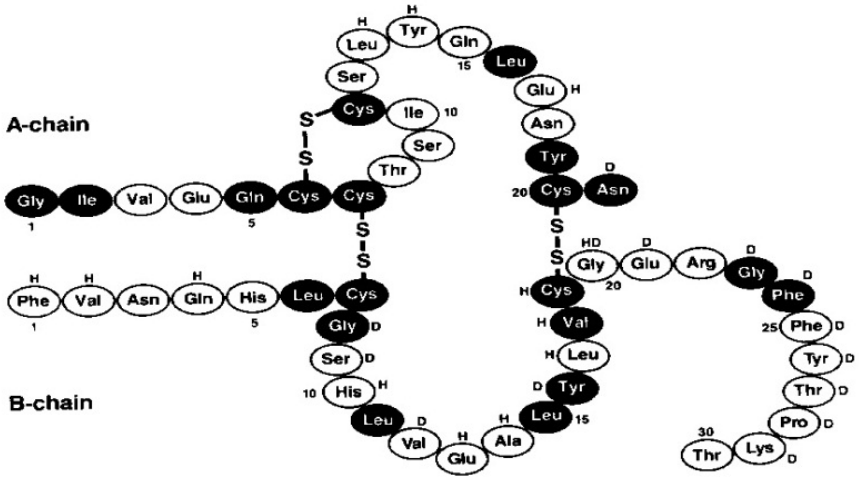

Figure 1: Structural formula of human insulin

NOVOLIN 70/30 is a sterile, white and cloudy injectable suspension that contains insulin isophane human suspension (NPH) and insulin human injection (regular) for subcutaneous use. Each milliliter of NOVOLIN 70/30 contains 100 units of insulin human, dibasic sodium phosphate (1.9 mg), glycerin (16 mg), metacresol (1.5 mg), phenol (0.65 mg), protamine sulfate (approximately 0.25 mg), zinc (20.5 mcg/mL for the vial or 30.1 mcg for the FlexPen), and Water for Injection. Hydrochloric acid 2N and sodium hydroxide 2N may be added during manufacture to adjust the pH. The pH is 7.1-7.5.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The primary activity of insulin, including NOVOLIN 70/30, is the regulation of glucose metabolism. Insulins lower blood glucose by stimulating peripheral glucose uptake, especially by skeletal muscle and fat, and by inhibiting hepatic glucose production. Insulin inhibits lipolysis and proteolysis, and enhances protein synthesis.

12.2 Pharmacodynamics

The time course of insulin action (i.e., glucose lowering) may vary considerably in different individuals or within the same individual. NOVOLIN 70/30 is an intermediate-acting insulin with up to 24 hours duration of action. When injected subcutaneously, the glucose-lowering effect of NOVOLIN 70/30 begins approximately 30 minutes post-dose.

12.3 Pharmacokinetics

The pharmacokinetics of NOVOLIN 70/30 have been established.

The effects of gender, age, obesity, renal and hepatic impairment on the pharmacokinetics of NOVOLIN 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.

Human insulin is not mutagenic in the following *in vitro* tests: The chromosomal aberration assay in human lymphocytes, the micronucleus assay in mouse

polychromatic erythrocytes, and the mutation frequency assay in Chinese hamster cells.

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

NOVOLIN 70/30 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 0169-1837-11
	ReliOn® brand	NDC 0169-1837-02
3 mL single-patient-use FlexPen		NDC 0169-3007-15
	ReliOn® brand	NDC 0169-3007-25

The NOVOLIN 70/30 FlexPen dials in 1-unit increments.

16.2 Storage and Handling

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

Do not expose NOVOLIN 70/30 vials and NOVOLIN 70/30 FlexPen to excessive heat or light. Do not freeze. Do not use after the expiration date.

NOVOLIN 70/30 FlexPen must never be shared between patients, even if the needle is changed. Always remove and discard the needle after each injection from the NOVOLIN 70/30 FlexPen and store without a needle attached.

Patients using NOVOLIN 70/30 vials, must never share needles or syringes with another person. Always use a new disposable syringe or needle for each injection to prevent contamination.

Table 2: Storage Conditions and Expiration Dates for NOVOLIN 70/30

	Not In-use (Unopened) Refrigerated (36°F - 46°F [2°C - 8°C])	**Not In-use (Unopened) Room Temperature (see temperature below)**	**In-use (Opened) Room Temperature (see temperature below)**
10 mL multiple-dose vial	Until expiration date	42 days up to **77°F (25°C)**	42 days up to **77°F (25° C)** (Do not refrigerate)
3 mL single-patient-use FlexPen	Until expiration date	28 days up to **86°F (30°C)**	28 days up to **86°F (30°C)** (Do not refrigerate)

17 PATIENT COUNSELING INFORMATION

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

Never Share a NOVOLIN 70/30 FlexPen or Syringe between Patients

Advise patients using NOVOLIN 70/30 vials or NOVOLIN 70/30 FlexPen not to share needles, syringes, or FlexPen with another person. Sharing poses a risk for transmission of blood-borne pathogens *[see Warnings and Precautions (5.1)]*.

Hyperglycemia or Hypoglycemia

Inform patients that hypoglycemia is the most common adverse reaction with insulin. Instruct patients on self-management procedures including glucose monitoring, proper

injection technique, and management of hypoglycemia and hyperglycemia, especially at initiation of NOVOLIN 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 *[see Warnings and Precautions (5.3)]*.

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.

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)]*.

Hypoglycemia due to Medication Errors

Instruct patients to always check the insulin label before each injection to avoid mix-ups between insulin products *[see Warnings and Precautions (5.4)]*.

Hypersensitivity Reactions

Advise patients that hypersensitivity reactions have occurred with NOVOLIN 70/30. Inform patients on the symptoms of hypersensitivity reactions and to seek medical attention if they occur *[see Warnings and Precautions (5.5)]*.

Novolin®, FlexPen® and Novo Nordisk® are registered trademarks of Novo Nordisk A/S.

ReliOn® is a registered trademark of Walmart Inc. and is used under license by Novo Nordisk Inc.

Patent Information: http://novonordisk-us.com/products/product-patents.html

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1-800-727-6500 (Se habla español)

Patient Package Insert

Patient Information

NOVOLIN® 70/30 (NO-voe-lin)

(insulin isophane human and insulin human) injectable suspension

for subcutaneous use

Do not share your Novolin 70/30 FlexPen or syringes with other people, even

if the needle has been changed. You may give other people a serious infection or get a serious infection from them.

What is Novolin 70/30?

Novolin 70/30 is a man-made insulin that is used to control high blood sugar in adults and children with diabetes mellitus.

Who should not use Novolin 70/30?

Do not use Novolin 70/30 if you:

- are having an episode of low blood sugar (hypoglycemia).
- have an allergy to insulin isophane human, insulin human or any of the ingredients in Novolin 70/30. See the end of this Patient Information leaflet for a complete list of ingredients in Novolin 70/30.

Before using Novolin 70/30, tell your healthcare provider about all of your medical conditions, including if you:

- have liver or kidney problems.
- take other medicines, especially ones called TZDs (thiazolidinediones).
- have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs with Novolin 70/30.
- **are pregnant or plan to become pregnant.** Talk with your healthcare provider about the best way to control your blood sugar if you plan to become pregnant or while you are pregnant.
- **are breastfeeding or plan to breastfeed**. NOVOLIN 70/30 may pass into your breast milk. Talk with your healthcare provider about the best way to feed your baby while using NOVOLIN 70/30.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines,

vitamins, or herbal supplements.

Before you start using Novolin 70/30, talk to your healthcare provider about low blood sugar and how to

manage it.

How should I use Novolin 70/30?

- **Read the detailed Instructions for Use that comes with your Novolin 70/30.**
- Use Novolin 70/30 exactly as your healthcare provider tells you to. Your healthcare provider should tell you how much Novolin 70/30 to use and when to use it.
- Use Novolin 70/30 about **30 minutes** before eating a meal.
- Know the type, strength, and amount of insulin you use. **Do not** change the type, or amount of insulin you use unless your healthcare provider tells you to. The amount of insulin and the best time for you to take your insulin may need to change if you use different types of insulin.
- Check your insulin label each time you give your injection to make sure you are using the correct insulin.
- Inject Novolin 70/30 under the skin (subcutaneously) in your stomach area, buttocks, upper legs (thighs) or upper arms. **Do not** inject Novolin 70/30 into your vein (intravenously) or use in an insulin infusion pump.
- **Do not** mix Novolin 70/30 with any other insulins or liquids.
- Change (rotate) your injection site within the area you choose with each dose to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the injection sites.
  - **Do not** use the exact same spot for each injection.
  - **Do not** inject where the skin has pits, is thickened, or has lumps.
  - **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or

damaged skin.
- **Check your blood sugar levels.** Ask your healthcare provider what your blood sugars should be and when you should check your blood sugar levels.

Keep Novolin 70/30 and all medicines out of the reach of children.

Your dose of Novolin 70/30 may need to change because of:

- change in level of physical activity or exercise, weight gain or loss, increased stress, illness, change in diet, or because of other medicines you take.

What should I avoid while using Novolin 70/30?

While using Novolin 70/30 **do not:**

- drive or operate heavy machinery until you know how Novolin 70/30 affects you.
- drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

What are the possible side effects of Novolin 70/30?

Novolin 70/30 may cause serious side effects that can lead to death, including:

- **low blood sugar (hypoglycemia).** Signs and symptoms of low blood sugar may include:

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o dizziness or lightheadedness, sweating, confusion, headache, blurred vision, slurred speech, shakiness, fast heartbeat, anxiety, irritability or mood changes, hunger.
○ Your healthcare provider may prescribe a glucagon emergency kit so that others can give you an injection if your blood sugar becomes too low (hypoglycemia) and you are unable to take sugar by mouth.

- **severe allergic reaction (whole body reaction). Get medical help right away if you have any of these signs or symptoms of a severe allergic reaction:**
○ a rash over your whole body, have trouble breathing, a fast heartbeat, or sweating.
- **low potassium in your blood (hypokalemia).**
- **heart failure.** Taking certain diabetes pills called thiazolidinediones or "TZDs" with Novolin 70/30 may cause heart failure in some people. This can happen even if you have never had heart failure or heart problems before. If you already have heart failure it may get worse while you take TZDs with Novolin 70/30. Your healthcare provider should monitor you closely while you are taking TZDs with Novolin 70/30. Tell your healthcare provider if you have any new or worse symptoms of heart failure including:

o shortness of breath, swelling of your ankles or feet, sudden weight gain.

Treatment with TZDs and Novolin 70/30 may need to be adjusted or stopped by your healthcare provider if you have new or worse heart failure.

Get emergency medical help if you have:
- severe hypoglycemia needing hospitalization or emergency room care, and be sure to tell the hospital staff the units of Novolin 70/30 your healthcare provider has prescribed for you.
- trouble breathing, shortness of breath, fast heartbeat, swelling of your face, tongue, or throat, sweating, extreme drowsiness, dizziness, confusion.

The most common side effects of Novolin 70/30 include:
- low blood sugar (hypoglycemia), allergic reactions including reactions at your

injection site, skin thickening or pits at the injection site (lipodystrophy), weight gain, and swelling (edema) in hands or feet.

These are not all of the possible side effects of Novolin 70/30. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of Novolin 70/30

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. **Do not** use Novolin 70/30 for a condition for which it was not prescribed. **Do not** give Novolin 70/30 to other people, even if they have the same symptoms you have. It may harm them.

This Patient Information leaflet summarizes the most important information about Novolin 70/30. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Novolin 70/30 that is written for healthcare providers. For more information, call 1-800-727-6500 or go to www.novonordisk-us.com.

What are the ingredients in Novolin 70/30?

Active ingredient: 70% insulin isophane human and 30% insulin human

Inactive ingredients: dibasic sodium phosphate, glycerin, metacresol, phenol, protamine sulfate, zinc, Water for Injection. Hydrochloric acid and sodium hydroxide may be added to adjust the pH.

Novolin®, FlexPen® and Novo Nordisk® are registered trademarks of Novo Nordisk A/S.

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Manufactured by:

Novo Nordisk Inc.

800 Scudders Mill Road

Plainsboro, New Jersey 08536

U.S. License Number 1261

For information about Novolin 70/30 contact:

Novo Nordisk Inc.

800 Scudders Mill Road

Plainsboro, New Jersey 08536

1-800-727-6500 (Se habla español)

www.novonordisk-us.com

This Patient Information has been approved by the U.S. Food and Drug Administration.
Revised: 11/2022

INSTRUCTIONS FOR USE

Novolin® 70/30

(insulin isophane human and insulin human)

injectable suspension, for subcutaneous use

10 mL multiple-dose vial (100 units/mL, U-100)

Before starting, gather all of the supplies that you will need to use for preparing and giving your insulin injection.

Never re-use syringes and needles.

How should I use the Novolin 70/30 vial?

1. Check to make sure that you have the correct type of insulin.
2. Look at the vial and the insulin. The insulin should be a cloudy or milky suspension. The tamper-resistant cap should be in place before the first use. If the cap had been removed before your first use of the vial, or if the precipitate (the white deposit at the bottom of the vial) has become lumpy or granular in appearance or has formed a deposit of solid particles on the wall of the vial, do not use it and call Novo Nordisk at 1-800-727-6500.
3. Wash your hands with soap and water. If you clean your injection site with an alcohol swab, let the injection site dry before you inject. Talk with your healthcare provider about how to rotate injection sites and how to give an injection. Novolin 70/30 can be injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs (thighs), or upper arms. Change (rotate) your injection sites within the area you choose for each dose to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the injection sites. **Do not** inject where the skin has pits, is thickened, or has lumps. **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
4. If you are using a new vial, pull off the tamper-resistant cap. Wipe the rubber stopper with an alcohol swab.
5. Roll the vial gently 10 times in your hands to mix it. This procedure should be carried out with the vial in a horizontal position. The rolling procedure must be repeated until the suspension appears uniformly white and cloudy. Shaking right before the dose is drawn into the syringe may cause bubbles or froth, which could cause you to draw up the wrong dose of insulin.
6. Pull back the plunger on the syringe until the black tip reaches the marking for the number of units you will inject.
7. Push the needle through the rubber stopper of the vial, and push the plunger all the way in to force air into the vial.
8. Turn the vial and syringe upside down and slowly pull the plunger back to a few units beyond the correct dose.
9. If there are any air bubbles, tap the syringe gently with your finger to raise the air bubbles to the top. Then slowly push the plunger to the marking for your correct dose. This process should move any air bubbles present in the syringe back into the vial.
10. Check to make sure you have the right dose of Novolin 70/30 in the syringe.
11. Pull the syringe with needle out of the vial's rubber stopper.
12. Your doctor should tell you if you need to pinch the skin before inserting the needle. This can vary from patient to patient, so it is important to ask your doctor if you did not receive instructions on pinching the skin. Insert the needle into the skin. Press the plunger of the syringe to inject the insulin. When you are finished injecting the insulin, pull the needle out of your skin. You may see a drop of Novolin 70/30 at the needle tip. This is normal and has no effect on the dose you just received. If you see blood after you take the needle out of your skin, press the injection site lightly with a piece of gauze or an alcohol wipe. **Do not rub the area.**
13. After your injection, do not recap the needle. Place used syringes, needles and used insulin vials in a disposable puncture-resistant sharps container, or some type of hard plastic or metal container with a screw on cap such as a detergent bottle or coffee can.
14. Ask your healthcare provider about the right way to throw away used syringes and needles. There may be state or local laws about the right way to throw away used syringes and needles. Do not throw away used needles and syringes in household trash or recycle.

How should I store Novolin® 70/30?

- **Do not** freeze Novolin 70/30. **Do not** use Novolin 70/30 if it has been frozen.
- Keep Novolin **70/30** away from heat or light.
- **All unopened vials:**
  - Store unopened Novolin 70/30 vials in the refrigerator at 36°F to 46°F (2°C to 8°C).
  - Unopened vials may be used until the expiration date printed on the label, if they

have been stored in the refrigerator.
- Unopened vials should be thrown away after 42 days, if they are stored at room temperature up to 77˚F (25˚C).

- **After vials have been opened:**
- Opened Novolin 70/30 vials can be stored at room temperature up to 77˚F (25˚C). Do not refrigerate.
- Throw away all opened Novolin 70/30 vials after 42 days, even if they still have insulin left in them.

This Patient Instructions for Use has been approved by the Food and Drug Administration.

Manufactured by:

Novo Nordisk Inc.

800 Scudders Mill Road

Plainsboro, New Jersey 08536

1-800-727-6500

U.S. License Number 1261

Revised: 11/2022

INSTRUCTIONS FOR USE

Novolin® 70/30 FlexPen®

(insulin isophane human and insulin human)

injectable suspension, for subcutaneous use

Introduction

Please read the following instructions carefully before using your Novolin 70/30 FlexPen.

Do not share your Novolin 70/30 FlexPen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.

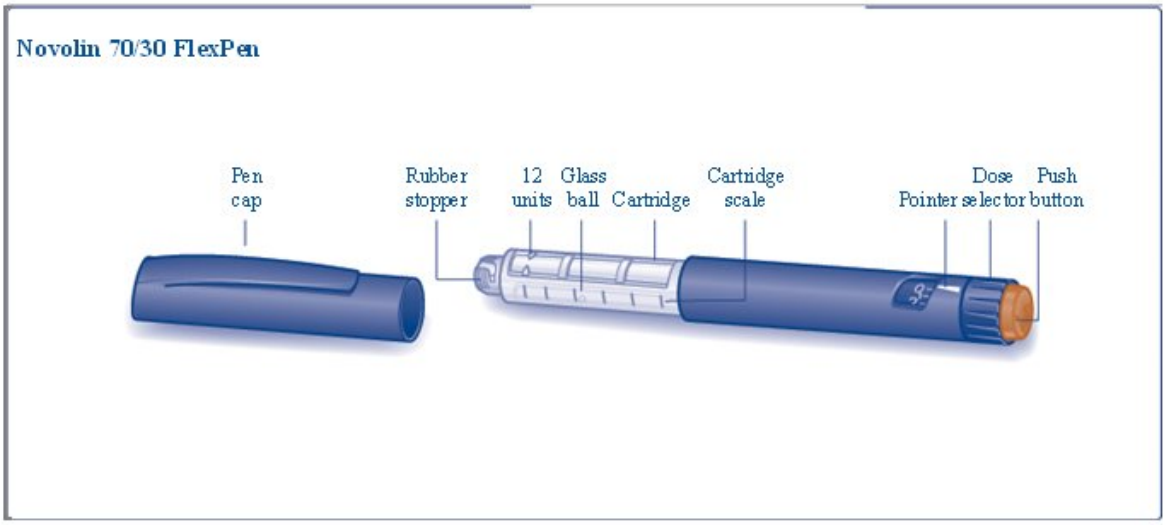
Novolin 70/30 FlexPen is a disposable dial-a-dose, single-patient-use, insulin pen. You can select doses from 1 to 60 units in increments of 1 unit. Novolin 70/30 FlexPen is designed to be used with NovoFine, NovoFine Plus or NovoTwist needles.

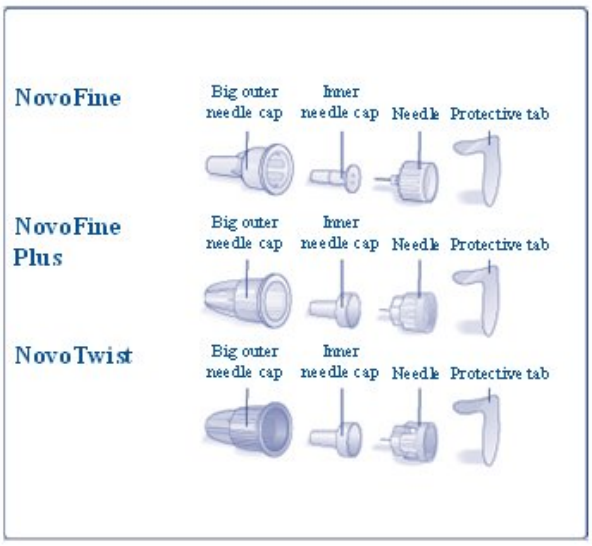
People who are blind or have vision problems should not use Novolin 70/30 FlexPen without help from a person trained to use Novolin 70/30 FlexPen.

Getting ready

Make sure you have the following items:

- Novolin 70/30 FlexPen
- New NovoFine, NovoFine Plus or NovoTwist needle
- Alcohol swab
- Gauze pad



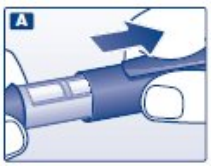


Preparing your Novolin 70/30 FlexPen

Wash your hands with soap and water. Before you start to prepare your injection, check the label to make sure that you are taking the right type of insulin. This is especially important if you take more than 1 type of insulin. Novolin 70/30 should look white and cloudy after mixing.

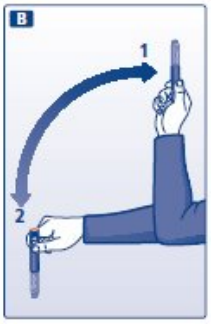
A. Let the insulin reach room temperature before you use it. This makes it easier to mix.

Pull off the pen cap (see diagram A).



B. Gently move the pen up and down twenty times between position **1** and **2** as shown, so the glass ball moves from one end of the cartridge to the other (see diagram B).

Repeat moving the pen until the liquid appears white and cloudy. Do not use the pen if the liquid appears discolored or contains particles.



For every following injection move the pen up and down between positions 1 and 2 at least ten times until the liquid appears white and cloudy.

After mixing, complete all the following steps of the injection right away. If there is a delay, the insulin will need to be mixed again.

Wipe the rubber stopper with an alcohol swab.

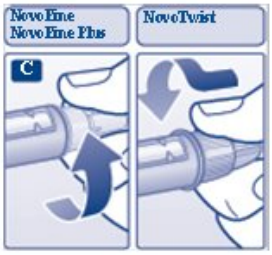
⚠ Before you inject, there must be at least 12 units of insulin left in the cartridge to make sure the remaining insulin is evenly mixed. If there are less than 12 units left in your Novolin 70/30 FlexPen, use a new pen.

Attaching the needle

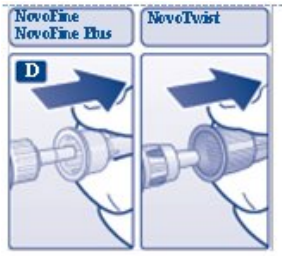
C. Remove the protective tab from a disposable needle.

Screw the needle tightly onto your Novolin 70/30 FlexPen. It is important that the needle is put on straight (see diagram C).

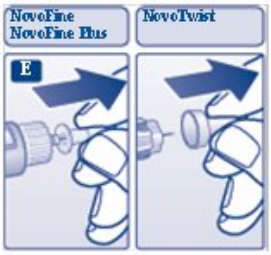
Never place a disposable needle on your Novolin 70/30 FlexPen until you are ready to take your injection.



D. Pull off the big outer needle cap (see diagram D).



E. Pull off the inner needle cap and dispose of it (see diagram E).



⚠

Always use a new needle for each injection to help ensure sterility and prevent blocked needles. Do not reuse or share your needles with other people. You may give other people a serious infection, or get a serious infection from them.

⚠ Be careful not to bend or damage the needle before use.

⚠ To reduce the risk of unexpected needle sticks, **never put the inner needle cap back on the needle.**

Giving the airshot before each injection

Before each injection small amounts of air may collect in the cartridge during normal use. To avoid injecting air and to make sure you take the right dose of insulin:

F. Turn the dose selector to select 2 units (see diagram F).

G. Hold your Novolin 70/30 FlexPen with the needle pointing up. Tap the cartridge gently with your finger a few times to make any air bubbles collect at the top of the cartridge (see diagram G).

H. Keep the needle pointing upwards, press the push-button all the way in (see diagram H). The dose selector returns to 0.

A drop of insulin should appear at the needle tip. If not, change the needle and repeat the procedure no more than 6 times.

If you do not see a drop of insulin after 6 times, do not use the Novolin 70/30 FlexPen and contact Novo Nordisk at 1-800-727-6500.

A small air bubble may remain at the needle tip, but it will not be injected.

Selecting your dose

Check and make sure that the dose selector is set at 0.

I. Turn the dose selector to the number of units you need to inject. The pointer should line up with your dose.

The dose can be corrected either up or down by turning the dose selector in either direction until the correct dose lines up with the pointer (see diagram I). When turning the dose selector, be careful not to press the push-button as insulin will come out.

You cannot select a dose larger than the number of units left in the cartridge.

You will hear a click for every single unit dialed. Do not set the dose by counting the number of clicks you hear.

⚠ Do not use the cartridge scale printed on the cartridge to measure your dose of insulin.

Giving the injection

Give the injection exactly as shown to you by your healthcare provider. Your healthcare provider should tell you if you need to pinch the skin before injecting. Wipe the skin with an alcohol swab and let the area dry.

Novolin 70/30 can be injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs (thighs), or upper arms.

For each injection, change (rotate) your injection site within the area of skin that you use. Change (rotate) your injection sites within the area you choose for each dose to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the injection sites. **Do not** use the same injection site for each injection. **Do not** inject where the skin has pits, is thickened, or has lumps. **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars

or damaged skin.

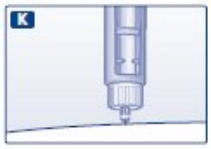
J. Insert the needle into your skin.

Inject the dose by pressing the push-button all the way in until the 0 lines up with the pointer (see diagram J). Be careful only to push the button when injecting.

Turning the dose selector will not inject insulin.

K. Keep the needle in the skin for at least 6 seconds, and keep the push-button pressed all the way in until the needle has been pulled out from the skin (see diagram K). This will make sure that the full dose has been given.

You may see a drop of insulin at the needle tip. This is normal and has no effect on the dose you just received. If blood appears after you take the needle out of your skin, press the injection site lightly with a gauze pad or an alcohol swab. **Do not rub the area.**



After the injection

Do not recap the needle. Recapping can lead to a needle stick injury. Remove the needle from the Novolin 70/30 FlexPen after each injection and dispose of it. This helps to prevent infection, leakage of insulin, and will help to make sure you inject the right dose of insulin.

If you do not have a sharps container, carefully slip the needle into the outer needle cap. Safely remove the needle and throw it away as soon as you can.

- The used Novolin 70/30 FlexPen may be thrown away in your household trash after you have removed the needle.
- Put your used needles in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles in your household trash.
- If you do not have a FDA-cleared sharps disposal container, you may use a household container that is:
    - made of a heavy-duty plastic
    - can be closed with a tight-fitting, puncture-resistant lid, without sharps being able to come out
    - upright and stable during use
    - leak-resistant
    - properly labeled to warn of hazardous waste inside the container
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about safe sharps disposal, and for

specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.
Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this. Do not recycle your used sharps disposal container.

- When there is not enough medicine left in your Novolin 70/30 FlexPen for your prescribed dose, the Novolin 70/30 FlexPen may be thrown away in your household trash after you have removed the needle. The Novolin 70/30 FlexPen prevents the cartridge from being completely emptied. It is designed to deliver 300 units.

L. Put the pen cap on the Novolin 70/30 FlexPen and store the Novolin 70/30 FlexPen without the needle attached (see diagram L). Storing without the needle attached helps prevent leaking, blocking of the needle, and air from entering the Pen.

How should I store Novolin 70/30 FlexPen?

- **Do not** freeze Novolin 70/30. **Do not** use Novolin 70/30 if it has been frozen.
- Keep Novolin 70/30 away from heat and light.
- **Until first use:**
  - Store unused Novolin 70/30 FlexPen in the refrigerator at 36°F to 46°F (2°C to 8°C).
  - Unused Novolin 70/30 FlexPen may be used until the expiration date printed on the label, if kept in the refrigerator at 36°F to 46°F (2°C to 8°C).
  - Unused Novolin 70/30 FlexPen stored at room temperature should be thrown away after 28 days.
- **In-use:**
  - Store the Novolin 70/30 FlexPen you are currently using out of the refrigerator at room temperature up to 86°F (30°C) for up to 28 days.
  - The Novolin 70/30 FlexPen you are using should be thrown away after 28 days, even if it still has insulin left in it.
  - Store the Novolin 70/30 FlexPen without the needle attached.

Maintenance

For the safe and proper use of your Novolin 70/30 FlexPen be sure to handle it with care. Avoid dropping your Novolin 70/30 FlexPen as it may damage it. If you are concerned that your Novolin 70/30 FlexPen is damaged, use a new one. You can clean the outside of your Novolin 70/30 FlexPen by wiping it with a damp cloth. Do not soak or wash your Novolin 70/30 FlexPen as it may damage it. Do not refill your Novolin 70/30 FlexPen.

⚠ Remove the needle from Novolin 70/30 FlexPen after each injection. This helps to ensure sterility, prevent leakage of insulin, and will help to make sure you inject the right dose of insulin for future injections.

⚠ Be careful when handling used needles to avoid needle sticks and transfer of infectious diseases.

⚠ Keep your Novolin 70/30 FlexPen and needles out of the reach of children.

⚠ Use Novolin 70/30 FlexPen as directed to treat your diabetes.

Do not share your Novolin 70/30 FlexPen or needles with other people. You may give other people a serious infection, or get a serious infection from them.

Always use a new needle for each injection.

Novo Nordisk is not responsible for harm due to using this insulin pen with products not recommended by Novo Nordisk.

As a precautionary measure, always carry a spare insulin delivery device in case your Novolin 70/30 FlexPen is lost or damaged.

Remember to keep the disposable Novolin 70/30 FlexPen with you. Do not leave it in a car or other location where it can get too hot or too cold.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured by:

Novo Nordisk Inc.

800 Scudders Mill Road

Plainsboro, New Jersey 08536

1-800-727-6500

U.S. License Number 1261

Revised: 11/2022

PRINCIPAL DISPLAY PANEL – 10 mL Vial

NDC **0169-1837-11**

Novolin®***70/30***

(insulin isophane human and insulin

human) injectable suspension

100 units/mL (U-100)

For subcutaneous use only

10 mL multiple-dose vial

Novo Nordisk®

PRINCIPAL DISPLAY PANEL – 10 mL Vial ReliOn

NDC **0169-1837-02**

Novolin® ***70/30***

(insulin isophane human and insulin human)

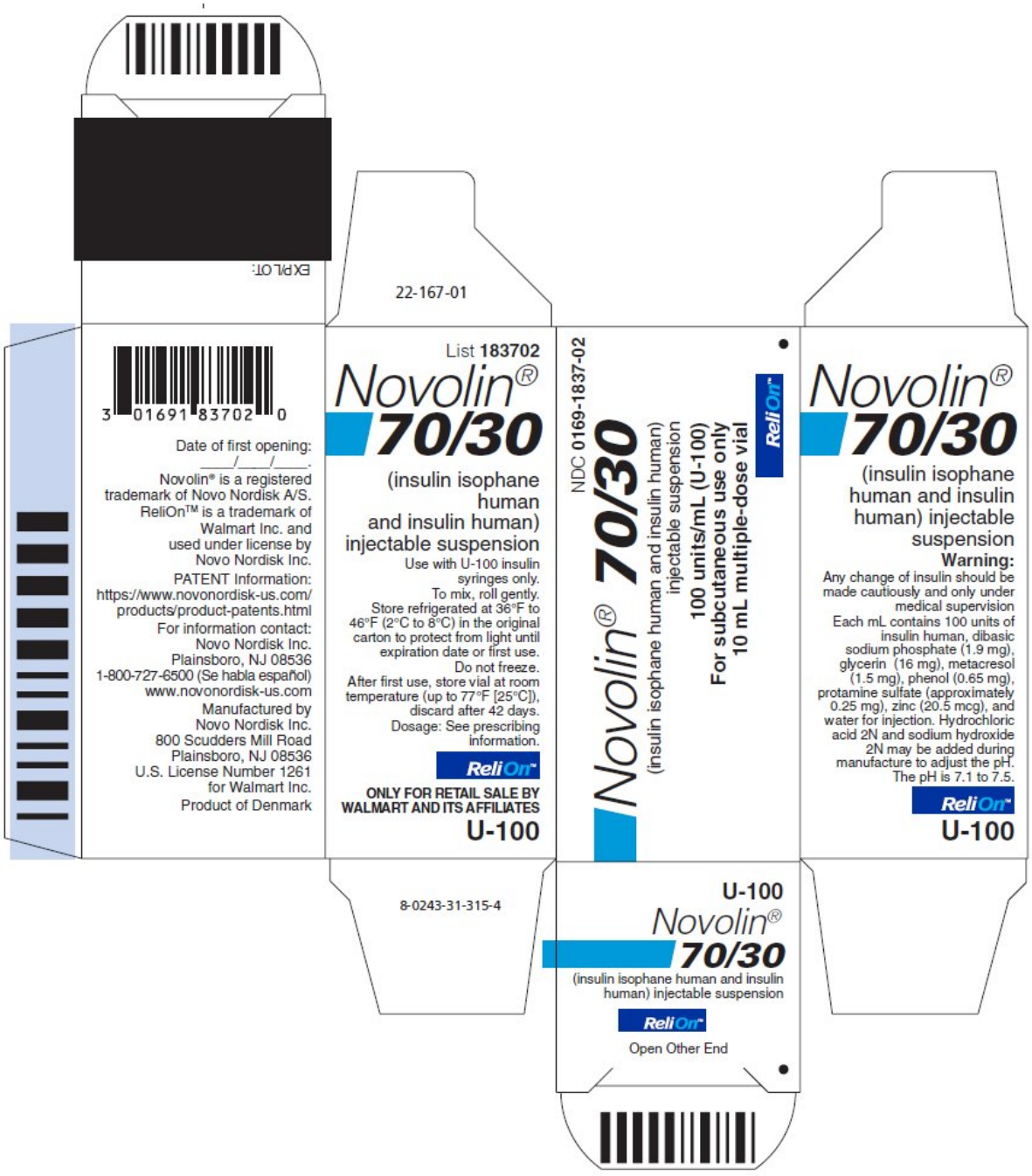
injectable suspension

100 units/mL (U-100)

For subcutaneous use only

10 mL multiple-dose vial

ReliOn™



PRINCIPAL DISPLAY PANEL – 3 mL FlexPen

NDC 0169-3007-15

List: 300715

Novolin® 70/30

FlexPen®

(insulin isophane human and insulin human)

injectable suspension

For Single-Patient-Use Only

100 units/mL (U-100)

5×3 mL Prefilled Pens

For subcutaneous use only

Recommended for use with NovoFine® or NovoFine® Plus disposable needles.

Store unopened pens refrigerated at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light until expiration date or first use. Do not freeze. After first use, store used pen at room temperature (up to 86°F [30°C]), discard after 28 days.

Dispense in this sealed carton.

Shake carefully before using.

See enclosed insert for proper technique.

70/30

novo nordisk®

PRINCIPAL DISPLAY PANEL – 3 mL FlexPen ReliOn

NDC 0169-3007-25

List: 300725

Novolin® 70/30

FlexPen®

(insulin isophane human and insulin human)

injectable suspension

For Single-Patient-Use Only

100 units/mL (U-100)

5×3 mL Prefilled Pens

For subcutaneous use only

Recommended for use with NovoFine® or NovoFine® Plus disposable needles.

Store unopened pens refrigerated at 36°F to 46°F (2°C to 8°C) in the original carton to protect from light until expiration date or first use. Do not freeze.

After first use, store used pen at room temperature (up to 86°F [30°C]), discard after 28 days.

Dispense in this sealed carton.

Shake carefully before using.

See enclosed insert for proper technique.

70/30

ReliOn™

NOVOLIN 70/30

human insulin injection, suspension

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0169-1837
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
INSULIN HUMAN (UNII: 1Y17CTI5SR) (INSULIN HUMAN - UNII:1Y17CTI5SR)	INSULIN HUMAN	100 [iU] in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
GLYCERIN (UNII: PDC6A3C0OX)	
METACRESOL (UNII: GGO4Y809LO)	
PHENOL (UNII: 339NCG44TV)	
PROTAMINE SULFATE (UNII: 0DE9724IHC)	

ZINC (UNII: J41CSQ7QDS)	
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0169-1837-11	1 in 1 CARTON	06/25/1991	
1		10 mL in 1 VIAL; Type 0: Not a Combination Product		
2	NDC:0169-1837-02	1 in 1 CARTON	06/25/1991	
2		10 mL in 1 VIAL; Type 0: Not a Combination Product		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA019991	06/25/1991	

NOVOLIN 70/30

human insulin injection, suspension

Product Information

Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0169-3007
Route of Administration	SUBCUTANEOUS		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
INSULIN HUMAN (UNII: 1Y17CTI5SR) (INSULIN HUMAN - UNII:1Y17CTI5SR)	INSULIN HUMAN	100 [iU] in 1 mL

Inactive Ingredients

Ingredient Name	Strength
SODIUM PHOSPHATE, DIBASIC, UNSPECIFIED FORM (UNII: GR686LBA74)	
GLYCERIN (UNII: PDC6A3C0OX)	
METACRESOL (UNII: GGO4Y809LO)	
PHENOL (UNII: 339NCG44TV)	
PROTAMINE SULFATE (UNII: 0DE9724IHC)	
ZINC (UNII: J41CSQ7QDS)	
WATER (UNII: 059QF0KO0R)	
HYDROCHLORIC ACID (UNII: QTT17582CB)	
SODIUM HYDROXIDE (UNII: 55X04QC32I)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0169-3007-15	5 in 1 CARTON	06/01/2018	
1	NDC:0169-3007-01	3 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

2	NDC:0169-3007-25	5 in 1 CARTON	06/01/2018	
2	NDC:0169-3007-12	3 mL in 1 SYRINGE, PLASTIC; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
BLA	BLA019991	06/01/2018	

Labeler - Novo Nordisk Pharmaceutical Industries, LP (622920320)

Revised: 11/2022

Novo Nordisk Pharmaceutical Industries, LP