**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 (human insulin isophane suspension and human insulin injection), for subcutaneous use

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**CONTRAINDICATIONS**

Never share a NOVOLIN® 70/30 FlexPen® or any of its excipients (4)

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**WARNINGS AND PRECAUTIONS**

Never share a NOVOLIN® 70/30 FlexPen® or syringe between patients, even if the needle is changed. (5.1)

---

**DRUG INTERACTIONS**

- Drugs that may increase the risk of hypoglycemia: antidiabetic agents, ACE inhibitors, angiotensin II receptor blocking agents, diisopropylamine, fibrate, fluoxetine, monoamine oxidase inhibitors, pentoxifylline, pramlintide, salicylates, somatostatin analog (e.g., octreotide), and sulfonamide antibiotics. (7)

- Drugs that may decrease the blood glucose lowering effect: atypical antipsychotics, corticosteroids, danazol, diuretics, estrogens, glucagon, isoniazid, niacin, oral contraceptives, phenothiazines, progestogens (e.g., oral contraceptives), protease inhibitors, somatropin, sympathomimetic agents (e.g., albuterol, ephedrine, terbutaline), and thyroid hormones. (7)

- Drugs that may increase or decrease the blood glucose lowering effect: alcohol, beta-blockers, clonidine, lithium salts, and pentamidine. (7)

- Drugs that may blunt the signs and symptoms of hypoglycemia: beta-blockers, clonidine, guanethidine, and reserpine. (7)

---

**ADVERSE REACTIONS**

Adverse reactions observed with NOVOLIN® 70/30 include hypoglycemia, allergic reactions, injection site reactions, edema, weight gain and renal impairment. (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.

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**INDICATIONS AND USAGE**

Injectable suspension: NOVOLIN® 70/30 100 units per mL (U-100). 70% human insulin isophane and 30% human insulin, is available as:
- 10 mL multiple-dose vial (3)
- 3 mL single-patient-use NOVOLIN® 70/30 FlexPen® (3)

---

**CONTRAINdications**

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

---

**DOSE FORMS AND STRENGTHS**

Injectable suspension: NOVOLIN® 70/30 100 units per mL (U-100). 70% human insulin isophane and 30% human insulin, is available as:
- 10 mL multiple-dose vial (3)
- 3 mL single-patient-use NOVOLIN® 70/30 FlexPen® (3)

---

**WARNINGs AND PRECAUTIONs**

- Never share a NOVOLIN® 70/30 FlexPen® or syringe between patients, even if the needle is changed. (5.1)
- Hypoglycemia 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)

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**Patient Counseling Information**

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

Revised: 11/2019
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 enclosed. 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 Hypoglycemia 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 (5.2). Repeated insulin injections into areas of lipodystrophy or localized cutaneous amyloidosis have been reported to result in hypoglycemia, 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 insulin therapies, 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 an individual 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 individual and change over time in the same individual. Symptomatic awareness of hypoglycemia may be less pronounced in patients with longstanding diabetes in patients with diabetic nerve disease, 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 insulin preparations, 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 composition or timing of meals), changes in level of physical activity, or changes to co-administered medication (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 and Allergic 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, or hypotension, tachycardia, or diarrhea. 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 (see Contraindications (5.5)).
7 DRUG INTERACTIONS

Table 1: Clinically Significant Drug Interactions with NOVOLIN® 70/30

<table>
<thead>
<tr>
<th>Drugs that May Increase the Risk of Hypoglycemia</th>
<th>Drugs:</th>
<th>Antidiabetic agents, ACE inhibitors, angiotensin II receptor blocking agents, diisopyramide, fibrates, fluoxetine, monoamine oxidase inhibitors, pentoxifylline, primidone, salicylates, somatostatin analog (e.g., octreotide), and sulfonamide antibiotics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention:</td>
<td>Dose adjustment and increased frequency of glucose monitoring may be required when NOVOLIN® 70/30 is co-administered with these drugs.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drugs that May Increase the Blood Glucose Lowering Effect of NOVOLIN® 70/30</th>
<th>Drugs:</th>
<th>Portable antipsychotics (e.g., olanzapine and clozapine), corticosteroids, danazol, diuretics, estrogens, glucagon, iron, insulin, oral contraceptives, phenothiazines, progesterone (e.g., oral contraceptives), prostate inhibitors, somatropin, sympathomimetic agents (e.g., albuterol, ephedrine, terbutaline), and thyroid hormones.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention:</td>
<td>Dose adjustment and increased frequency of glucose monitoring may be required when NOVOLIN® 70/30 is co-administered with these drugs.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drugs that May Increase or Decrease the Blood Glucose Lowering Effect of NOVOLIN® 70/30</th>
<th>Drugs:</th>
<th>Alcohol, beta-blockers, clonidine, and lithium salts. Pentamidine may cause hypoglycemia, which may sometimes be followed by hyperglycemia.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention:</td>
<td>Dose adjustment and increased frequency of glucose monitoring may be required when NOVOLIN® 70/30 is co-administered with these drugs.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Drugs that May blunt Signs and Symptoms of Hypoglycemia</th>
<th>Drugs:</th>
<th>Beta-blockers, clonidine, guanethidine, and reserpine.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intervention:</td>
<td>Increased frequency of glucose monitoring may be required when NOVOLIN® 70/30 is co-administered with these drugs.</td>
<td></td>
</tr>
</tbody>
</table>

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. 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 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)).

11 DESCRIPTION

NOVOLIN® 70/30 (human insulin isophane suspension and human insulin injection) is a mixture of 70% of human insulin isophane, an intermediate-acting human insulin, and 30% of human insulin, a short-acting human insulin. Human insulins are produced by recombinant DNA technology, utilizing baker's yeast as the production organism. NOVOLIN® 70/30 has the empirical formula C_{x}(baker's yeast) as the production organism. NOVOLIN® 70/30 is an intermediate-acting insulin with up to 28 days post-dose.

16.1 How Supplied

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

- 10 mL multiple-dose vial (opened) Refill brand NDC 0169-1837-11
- 3 mL single-patient use FlexPen® Refill brand NDC 0169-3007-25

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. Always use a new disposable syringe or needle for each injection to prevent contamination.

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.

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

<table>
<thead>
<tr>
<th>Preservative-Free Vial</th>
<th>Not In-Use (Unoccupied) Refrigerated Room Temperature</th>
<th>Not In-Use (Unoccupied) Room Temperature</th>
<th>In-Use (Open) Room Temperature</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mL multiple-dose vial</td>
<td>Until expiration date</td>
<td>42 days below 77°F (25°C)</td>
<td>Do not refrigerate.</td>
</tr>
<tr>
<td>3 mL single-patient use FlexPen®</td>
<td>Until expiration date</td>
<td>28 days below 86°F (30°C)</td>
<td>Do not refrigerate.</td>
</tr>
</tbody>
</table>
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)].

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ReliOn® brand manufactured by:
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US19LINM00001  December 2019
Patient Information

NOVOLIN® 70/30 (NO-voe-lin)
(human insulin isophane suspension and human insulin injection) 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 human insulin isophane, human insulin 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 planning 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. 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 muscle
(intramuscularly) 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:
  • 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 swelling.
• 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:
  • 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,
swelling, 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% human insulin isophane and 30% human insulin

Inactive ingredients: glycerol, metacresol, zine, phenol, disodium phosphate dicytrate, protamine
sulfate, water for injection, hydrochloric acid and sodium hydroyxide.

This Patient Information has been approved by the U.S. Food and Drug Administration.

Revised: 11/2019

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Manufactured by:
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DK-2880 Bagsvaerd, Denmark
For information about Novolin® 70/30 contact:
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800 Scudders Mill Road
Plainlsboro, New Jersey 08536
1-800-727-6500
www.novonordisk-us.com
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US19LINM00001 December 2019
Instructions For Use
Novolin® 70/30 FlexPen®
(human insulin isophane suspension and human insulin injection) 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 cleaned. 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

Novolin® 70/30 FlexPen®
- Pen cap
- Rubber stopper
- Glass ball
- Cartridge scale
- Pointer
- Push-button
- Dose selector

NovoFine®
- Big outer needle cap
- Inner needle cap
- Needle
- Protective tab

NovoFine® Plus
- Big outer needle cap
- Inner needle cap
- Needle
- Protective tab

NovoTwist®
- Big outer needle cap
- Inner needle cap
- Needle
- Protective tab

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 fingers 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 until the 0 lines return 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 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 return to 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 needle cap. Safely remove the needle and dispose of it away. If there is a delay, the insulin will need to be mixed again.

• Put your used needles in a FDA-cleared sharps disposal container.
• 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 below 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.
PATIENT INSTRUCTIONS FOR USE
Novolin® 70/30 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 below 77°F (25°C).
- After vials have been opened:
  - Opened Novolin® 70/30 vials can be stored at room temperature below 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.