HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use NOVOLOG® safely and effectively. See full prescribing information for NOVOLOG®.

NOVOLOG® (insulin aspart) injection, for subcutaneous or intravenous use

Initial U.S. Approval: 2000

——— INDICATIONS AND USAGE ———

• NOVOLOG® is rapid acting human insulin analog indicated to improve glycemic control in adults and pediatric patients with diabetes mellitus (1).

——— DOSAGE AND ADMINISTRATION ———

See Full Prescribing Information for important preparation, administration, and dosage instructions (2.1, 2.2, 2.3, 2.4, 2.5).

Subcutaneous injection (2.2):

- Inject subcutaneously within 5-10 minutes before a meal into the abdominal area, thigh, buttocks or upper arm.
- Rotate injection sites within the same region from one injection to the next to reduce the risk of lipodystrophy and localized cutaneous amyloidosis.
- Should generally be used in regimens with an intermediate- or long-acting insulin.

Continuous Subcutaneous Infusion (Insulin Pump) (2.2):

- Refer to the insulin infusion pump user manual to see if NOVOLOG® can be used. Use in accordance with the insulin pump instructions for use.
- Administer by continuous subcutaneous infusion using an insulin pump in a region recommended in the instructions from the pump manufacturer.
- Rotate the injection sites within the same region from one injection to the next to reduce the risk of lipodystrophy and localized cutaneous amyloidosis.
- Do not mix with other insulins or diluents in the pump.

Intravenous Administration (2.2):

- Dilute NOVOLOG® to concentrations from 0.05 unit/mL to 1 unit/mL insulin aspart in infusion systems using polypropylene infusion bags.
- NOVOLOG® is stable in infusion fluids such as 0.9% Sodium Chloride Injection, USP.
- Individualize and adjust the dosage of NOVOLOG® based on route of administration, the individual’s metabolic needs, blood glucose monitoring results and glycemic control goal (2.4).
- 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 (2.4).

——— DOSAGE FORMS AND STRENGTHS ———

Injection: 100 units/mL (U-100) of insulin aspart available as:
- 10 mL multiple-dose vial (3)
- 3 mL single-patient-use PenFill® prefilled cartridge for the 3 mL PenFill® cartridge device (3)
- 3 mL single-patient-use FlexPen® prefilled pen (3)
- 3 mL single-patient-use FlexTouch® prefilled pen (3)

——— CONTRAINDICATIONS ———

• During episodes of hypoglycemia (4).
• Hypersensitivity to NOVOLOG® or one of its excipients.

——— WARNINGS AND PRECAUTIONS ———

• Never share a NOVOLOG® FlexPen® or a NOVOLOG® FlexTouch®, PenFill® cartridge or PenFill® cartridge device 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 glucose monitoring with changes to: insulin dosage, concomitantly administered glucose lowering medications, meal pattern, physical activity; and in patients with renal or hepatic impairments and hypoglycemia unawareness (5.3).
• 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, may occur. Discontinue NOVOLOG®, treat, and monitor, if indicated (5.5).
• Hypokalemia: May be life-threatening. Monitor potassium levels in patients at risk of hypokalemia and treat if indicated (5.6).
• Fluid retention and heart failure with concomitant use of thiazolidinediones (TZDs): Observe for signs and symptoms of heart failure; consider dosage reduction or discontinuation if heart failure occurs (5.7).
• Hyperglycemia and Ketoacidosis Due to Insulin Pump Device Malfunction: Monitor glucose and administer NOVOLOG® by subcutaneous injection if pump malfunction occurs (5.8).

——— ADVERSE REACTIONS ———

Adverse reactions observed with NOVOLOG® include:
• Hypoglycemia, allergic reactions, local injection site reactions, lipodystrophy, rash, and pruritus (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 may increase the risk of hypoglycemia: antidiabetic agents, ACE inhibitors, angiotensin II receptor blocking agents, diisopropyl, fribates, fluoxetine, monoamine oxidase inhibitors, pentoxifylline, pramilidte, salicylates, somatostatin analog (e.g., octreotide), and sulfonamide antibiotics (7).
• Drugs that may decrease the blood glucose lowering effect: atypical antipsychotics, corticosteroids, danazol, diuretics, estrogen, glucagon, insulin, oral contraceptives, protease inhibitors, somatropin, sympathomimetic agents (e.g., albuterol, epinephrine, 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).

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

Revised: 02/2023

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2.3 Dosage Recommendations

Dosage modification may be needed when NOVOLG® is used concomitantly with certain other medications (see Drug Interactions (7)).

2.4 Instructions for Mixing NOVOLG® with Other Insulins

The table below includes instructions regarding mixing NOVOLG® with other insulins.

| Subcutaneous injection route | NOVOLG® | Other insulin
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Continuous subcutaneous infusion (Insulin Pump)</td>
<td>NOVOLG® may only be mixed with NPH insulin, withdrawn NOVOLG® into the syringe and inject immediately after mixing.</td>
<td>Other insulin</td>
</tr>
</tbody>
</table>

Continuous subcutaneous infusion (Insulin Pump) Do not mix NOVOLG® with any other insulin.

3 DOSAGE FORMS AND STRENGTHS

Injection: 100 units/mL (U-100) is a clear and colorless solution available as:

- 1 mL multiple-dose vial
- 3 mL single-patient-use FlexPen® prefilled cartridge for the 3 mL FlexPen® cartridge delivery device with NovoFine® disposable needles
- 3 mL single-patient-use FlexPen® prefilled pen
- 5 mL single-patient-use FlexTouch® prefilled pen

4 CONTRAINDICATIONS

- NOVOLG® is contraindicated:
  - During episodes of hypoglycemia (see Warnings and Precautions (5.3, 5.4))
  - In patients hypersensitive to NOVOLG® or one of its excipients (see Warnings and Precautions (5.5))

5 WARNINGS AND PRECAUTIONS

5.1 Never Share a NOVOLG® FlexPen®, NOVOLG® FlexTouch®, PenFill® Cartridge, or PenFill® Cartridge Device between Patients

- PenFill® cartridge devices should never be shared between patients, even if the needle is changed. Patients using NOVOLG® vials must never share needles or syringes with another person. Sharing poses a risk for transmission of blood-borne pathogens.

5.2 Hypoglycemia

Hypoglycemia is the most common adverse reaction of all insulins, including NOVOLG®. Severe hypoglycemia can cause seizures, may lead to irreversible brain damage, and can cause death. Hypoglycemia can impair concentration ability and reaction time, this may place an individual at risk in situations where these abilities are important (see Warnings and Precautions (5.3, 5.4)).

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, patients with diabetic nerve disease, in patients using subcutaneous insulin infusion systems, even if the needle is changed. Patients using NOVOLG® must be aware of the risk of hypoglycemia, and at the signs of hypoglycemia.

Risk Factors for Hypoglycemia

The risk of hypoglycemia after an injection is related to the duration of action of the insulin and, in general, is highest when the glucose lowering effect of the insulin is maximal. As with all insulins, the glucose lowering effect course of NOVOLG® may vary in different individuals or at different times in the same individual and depends on many conditions, including the area of injection as well as the injection site blood supply and temperature (see Clinical Pharmacology (12.2, 12.3)). Other factors which may increase the risk of hypoglycemia include changes in meal pattern (e.g., macronutrient content or timing of food intake), changes in renal or hepatic function or during acute illness (see Warnings and Precautions (5.3, 5.4) and How Supplied (16.2)).

5.3 Hypokalemia

Hypokalemia may occur with insulins, including NOVOLG®. Hypokalemia can impair concentration ability and reaction time, this may place an individual at risk in situations where these abilities are important (see Warnings and Precautions (5.4)).

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; increased frequency of blood glucose monitoring is recommended. Patients at higher risk for hypoglycemia and patients who have reduced symptomatic awareness of hypoglycemia; increased frequency of blood glucose monitoring is recommended.

5.4 Hypoglycemia Due to Medication Errors

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

5.5 Hypersensitivity Reactions

Severe, life-threatening, generalized allergy, including anaphylaxis, can occur with insulins, including NOVOLG®. If hypersensitivity reactions occur, discontinue NOVOLG®; treat per standard of care and monitor until symptoms and signs resolve (see Adverse Reactions (6)). NOVOLG® is contraindicated in patients who have had hypersensitivity reactions to insulin aspart or one of the excipients (see Contraindications (4)).

5.6 Hypokalemia

All insulins, including NOVOLG®, can 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-γ agonists

Thiazolidinediones (TZDs), which are peroxisome proliferator-activated receptor (PPAR-γ) agonists, can cause dose-related fluid retention, particularly when used in combination with insulin. Fluid retention may lead to or exacerbate heart failure. Patients treated with insulin, including NOVOLG®, and a PPAR-γ agonist should be observed for signs and symptoms of heart failure. If heart failure develops, it should be managed according to current cardiac care guidelines. Close monitoring for fluid retention or dose reduction of the PPAR-γ agonist must be considered.

5.8 Hyperglycemia and Ketoadecis Due to Insulin Pump Device Malfunction

Malfunction of the insulin pump or insulin infusion set or insulin degradation can rapidly lead to hyperglycemia and ketoadecis. Prompt identification and correction of the cause of hyperglycemia or ketoadecis is necessary. Interim subcutaneous injections with NOVOLG® may be required. Patients using continuous subcutaneous insulin infusion pump therapy must be trained to administer insulin by injection and have alternate insulin therapy available in case of pump failure (see How Supplied/Storage and Handling (16.2) and Patient Counseling Information (17)).

6 ADVERSE REACTIONS

The following adverse reactions are also discussed elsewhere:

- Hypoglycemia (see Warnings and Precautions (5.3, 5.4))
- Hypokalemia (see Warnings and Precautions (5.4))
- Hypersensitivity reactions (see Warnings and Precautions (5.5))
- Hypoglycemia (see Warnings and Precautions (5.6))

6.1 Clinical Trial Experience

Because clinical trials are conducted under widely varying designs, the adverse reaction rates reported in one clinical trial may not be easily compared with those rates reported in another clinical trial, and may not reflect the rates actually observed in clinical practice. The safety of NOVOLG® was evaluated in two treat-to-target trials of 6 months duration, conducted in patients with type 1 diabetes or type 2 diabetes (see Clinical Studies (14)). The data in Table 1 reflect the exposure of 598 patients with type 1 diabetes to NOVOLG® in one clinical trial with a mean exposure duration to NOVOLG® of 24 weeks. The mean age was 39 years. Fifty-one percent were male, 94% were Caucasian, 2% were Black and 4% were other races. The mean body mass index (BMI) was 25.6 kg/m². The mean duration of diabetes was 15.7 years and the mean HbA1c at baseline was 7.9%.

The data in Table 2 reflect the exposure of 91 patients with type 2 diabetes to NOVOLG® in one clinical trial with a mean exposure duration to NOVOLG® of 24 weeks. The mean age was 57 years. Sixty-three percent were male, 76% were Caucasian, 9% were Black and 15% were other races. The mean BMI was 29.7 kg/m². The mean duration of diabetes was 12.7 years and the mean HbA1c at baseline was 8.1%.

Common adverse reactions were defined as events that occurred in ≥5%, excluding hypoglycemia, of the population studied. Common adverse events that occurred at the same rate or greater for NOVOLG®-treated patients than in comparator-treated patients during clinical trials in patients with type 1 diabetes mellitus and type 2 diabetes mellitus (other than hypoglycemia) are listed in Table 1 and Table 2, respectively.

Table 1: Adverse reactions that occurred in a 5% of Type 1 Diabetes Mellitus Adult Patients treated with NOVOLG® and at the same rate or greater on NOVOLG® than on comparator

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Type 1 Diabetes Mellitus</th>
<th>NOVOLG® N (%)</th>
<th>Comparator N (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>12</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Injury accidental</td>
<td>11</td>
<td>10</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>7</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>5</td>
<td>3</td>
<td></td>
</tr>
</tbody>
</table>

NOVOLG® = insulín asparín injection

PKH (%) = Peri-Kidney Hypertension

Regular Human Insulin = NOVOLG® N (%) = 286

*Note: *Adverse reactions that occurred in ≥5% of Type 1 Diabetes Mellitus Adult Patients treated with NOVOLG® and at the same rate or greater on NOVOLG® than on comparator.
6.3 Post Marketing Experience

The following adverse reactions have been identified during post-approval use of NOVOLOG®. Based on these adverse reactions, it is not possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Medication errors have been reported in which insulin was accidentally substituted for NOVOLOG®. Medication errors have been reported in which insulin aspart has been accidentally substituted for insulin glargine.

Localized cutaneous amyloidosis at the injection site has occurred with insulin aspart. Hypoglycemia 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.

7 DRUG INTERACTIONS

The table below presents clinically significant drug interactions with NOVOLOG®.

<table>
<thead>
<tr>
<th>Drug Group</th>
<th>Example Drugs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antidiabetic agents</td>
<td>ACE inhibitors, angiotensin II receptor blocking agents, acipimox, fibrate, fluoxetine, monamine oxidase inhibitors, pentoxifylline, tramadol, salicylates, somatostatin analog (e.g., octreotide), and sulfonamide antibiotics.</td>
</tr>
<tr>
<td>Antihypertensives</td>
<td>Intensive monitoring and frequent monitoring may be required when NOVOLOG® is concomitantly administered with these drugs.</td>
</tr>
<tr>
<td>Diuretics</td>
<td>Intensive monitoring and frequent monitoring may be required when NOVOLOG® is concomitantly administered with these drugs.</td>
</tr>
<tr>
<td>Antidepressants</td>
<td>Increase the frequency of glucose monitoring may be required when NOVOLOG® is concomitantly administered with these drugs.</td>
</tr>
<tr>
<td>Oral anticoagulants</td>
<td>NOVOLOG® may cause hypoglycemia, which may sometimes be followed by hyperglycemia.</td>
</tr>
<tr>
<td>Oral hypoglycemics</td>
<td>NOVOLOG® may cause hypoglycemia, which may sometimes be followed by hyperglycemia.</td>
</tr>
<tr>
<td>Antipsychotics</td>
<td>NOVOLOG® may cause hypoglycemia, which may sometimes be followed by hyperglycemia.</td>
</tr>
<tr>
<td>Steroids</td>
<td>NOVOLOG® may cause hypoglycemia, which may sometimes be followed by hyperglycemia.</td>
</tr>
</tbody>
</table>

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

Available information from published randomized controlled trials with insulin aspart use during the second trimester of pregnancy have not reported an association with major birth defects or miscarriage and maternal hypoglycemia may recur after apparent clinical recovery. Hypokalemia must be treated promptly. The table below presents clinically significant drug interactions with NOVOLOG®.

Table 2: Adverse reactions that occurred in ≥ 5% of Type 2 Diabetes Mellitus Adult Patients treated with NOVOLOG® and at the same rate or greater on NOVOLOG® than on comparator

<table>
<thead>
<tr>
<th>Condition</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypotension</td>
<td>11 ± 7</td>
</tr>
<tr>
<td>Dysmorphia</td>
<td>10 ± 5</td>
</tr>
<tr>
<td>Sensory disturbance</td>
<td>9</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>8 ± 7</td>
</tr>
<tr>
<td>Chest pain</td>
<td>5 ± 3</td>
</tr>
<tr>
<td>Headache</td>
<td>5 ± 3</td>
</tr>
<tr>
<td>Skin disorder</td>
<td>5 ± 2</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>5 ± 5</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>5 ± 5</td>
</tr>
</tbody>
</table>

Severe Hypoglycemia

Hypoglycemia is the most commonly observed adverse reaction in patients using insulin, including NOVOLOG®. The rates of reported hypoglycemia depend on the definition of hypoglycemia used, diabetes type, insulin dose, intensity of glucose control, background therapies, and other intrinsic and extrinsic patient factors. For these reasons, comparing rates of hypoglycemia in clinical trials for NOVOLOG® with the incidence of hypoglycemia for other products may be misleading and also, may not be representative of hypoglycemia rates that will occur in clinical practice.

8.2 Lactation

Risk Summary

There are no data on the presence of NOVOLOG® in human milk, the effects on the breastfed infant, or the effect on milk production. One small published study reported that exogenous insulin, including insulin aspart, was present in human milk. However, there is insufficient information to determine the effects of insulin aspart on the breastfed infant. The developmental and health benefits of breastfeeding should be considered along with the mother’s clinical need for NOVOLOG®, and any potential adverse effects on the breastfed infant from NOVOLOG®, or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of NOVOLOG® to improve glycemic control have been established in pediatric patients with diabetes mellitus. Use of NOVOLOG® for this indication is based on extrapolation from adult studies and well-controlled study in 283 pediatric patients with type 1 diabetes mellitus aged 6 to 18 years and from studies in adults with diabetes mellitus.

8.5 Geriatric Use

Of the total number of patients (n=1,375) treated with NOVOLOG® in 3 controlled clinical studies, 2.6% (n=36) were ≥65 years of age or over. One of these patients had type 1 diabetes (18/125) and the other half had type 2 diabetes (18/30). The HbA1c response to NOVOLOG®, as compared to regular human insulin, did not differ by age.

8.6 Renal Impairment

Patients with renal impairment may be at increased risk of hypoglycemia and may require more frequent NOVOLOG® dose adjustment and more frequent blood glucose monitoring (see Warnings and Precautions (5.3) and Clinical Pharmacology (12.3)).

8.7 Hepatic Impairment

Patients with hepatic impairment may be at increased risk of hypoglycemia and may require more frequent NOVOLOG® dose adjustment and more frequent blood glucose monitoring (see Warnings and Precautions (5.3) and Clinical Pharmacology (12.3)).

10 OVERDOSAGE

Excess insulin administration may cause hypoglycemia and hypokalemia. Patients with excess insulin administration may require more frequent monitoring of blood glucose and potassium levels due to hypoglycemia and hypokalemia. Hypokalemia may require correction with potassium chloride.

11 DESCRIPTION

Insulin aspart is a rapid-acting human insulin analog homologous with insulin aspart (Novo Nordisk, Bagsvaerd, Denmark) with the exception of a substitution of the amino acid proline by aspartic acid in position B28, and is produced by recombinant DNA technology utilizing Saccharomyces cerevisiae (baker's yeast). Insulin aspart has the empirical formula C25H33N5O11S and a molecular weight of 855.8 Da.

8.6 Renal Impairment

Patients with renal impairment may be at increased risk of hypoglycemia and may require more frequent NOVOLOG® dose adjustment and more frequent blood glucose monitoring (see Warnings and Precautions (5.3) and Clinical Pharmacology (12.3)).

8.7 Hepatic Impairment

Patients with hepatic impairment may be at increased risk of hypoglycemia and may require more frequent NOVOLOG® dose adjustment and more frequent blood glucose monitoring (see Warnings and Precautions (5.3) and Clinical Pharmacology (12.3)).

10 OVERDOSAGE

Excess insulin administration may cause hypoglycemia and hypokalemia (see Warnings and Precautions (5.3) and Clinical Pharmacology (12.3)).

11 DESCRIPTION

Insulin aspart is a rapid-acting human insulin analog homologous with insulin aspart (Novo Nordisk, Bagsvaerd, Denmark) with the exception of a substitution of the amino acid proline by aspartic acid in position B28, and is produced by recombinant DNA technology utilizing Saccharomyces cerevisiae (baker's yeast). Insulin aspart has the empirical formula C25H33N5O11S and a molecular weight of 855.8 Da.

Figure 1. Structural formula of insulin aspart.
12. CLINICAL PHARMACOLOGY
12.1 Mechanism of Action

The primary activity of insulin, including NOVOLOG®, is the regulation of glucose metabolism. Insulin and its analogs 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 Pharmacokinetics

Pharmacokinetics of NOVOLOG® After Subcutaneous Administration

The pharmacokinetic profile of NOVOLOG® given subcutaneously in 22 patients with type 1 diabetes is shown in Figure 2. The maximum glucolowering effect of NOVOLOG® occurred between 1 and 3 hours after subcutaneous injection (0.1 units/kg). The duration of action for NOVOLOG® is 3 to 5 hours. The time course of action of insulin and insulin analogs such as NOVOLOG® may vary considerably in different individuals or within the same individual. The parameters of NOVOLOG® activity (time of onset, peak time and duration) as designated in Figure 2 should be considered only as general guidelines. The rate of insulin absorption and onset of activity is affected by the site of injection, exercise, and other variables [See Warnings and Precautions (5.3)].

A double-blind, randomized, two-way crossover study in 16 patients with type 1 diabetes demonstrated that intravenous infusion of NOVOLOG® resulted in a blood glucose profile that was similar to that after intravenous infusion with regular human insulin. NOVOLOG® or human insulin was infused until the patient's blood glucose decreased to 36 mg/dL, or until the patient demonstrated signs of hypoglycemia (rise in heart rate and onset of sweating), defined as the time of autonomic reaction (R) (see Figure 3).

Figure 2. Serial mean serum glucose collected up to 6 hours following a single 0.15 units/kg pre-meal dose of NOVOLOG® (solid curve) or regular human insulin (hatched curve) injected immediately before a meal in 22 patients with type 1 diabetes. A single subcutaneous dose of 0.08 units/kg NOVOLOG® resulted in a mean profile similar to that seen with regular human insulin.

Figure 3. Mean blood glucose profiles following intravenous infusion of NOVOLOG® (hatched curve) and regular human insulin (solid curve) in 16 patients with type 1 diabetes. *R represents the time of autonomic reaction.*

13. NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies of NOVOLOG® and regular human insulin in animals have not been performed to evaluate the carcinogenic potential of NOVOLOG®. In 52-week studies, Sprague-Dawley rats were dosed subcutaneously with NOVOLOG® at 10, 50, and 200 units/kg/day (approximately 2.8, 13.6, and 68 times the human dose on a body surface area basis, respectively). At a dose of 200 units/kg/day, NOVOLOG® increased the incidence of mammary gland tumors in females when compared to untreated controls. The relevance of these findings to humans is unknown. No adverse effects in the general testing in the following tests: Ames test, mouse lymphoma cell forward gene mutation test, human peripheral blood lymphocyte chromosome aberration test, in vivo microsomal test in mice, and in vitro V79 test in rat liver hepatocytes.

In fertility studies in male and female rats, at subcutaneous doses up to 200 units/kg/day (approximately 32 times the human subcutaneous dose, based on units/body surface area), no direct adverse effects on male and female fertility, or general reproductive performance of animals was observed.

13.2 Animal Toxicology and/or Pharmacology

In standard biological assays in mice and rabbits, one unit of NOVOLOG® has the same glucolowering effect as one unit of regular human insulin.

14. CLINICAL STUDIES

14.1 Overview of Clinical Studies

The safety and effectiveness of subcutaneous NOVOLOG® were compared to regular human insulin in 596 type 1 diabetes adult, 187 pediatric type 1 diabetes, and 91 adult type 2 diabetes patients using NPH as basal insulin (see Table 1). The reduction in glycated hemoglobin (HbA1c) was similar to regular human insulin.

The safety and effectiveness of NOVOLOG® administered by continuous subcutaneous insulin infusion (CSI) by external pump was compared to buffered regular human insulin (administered by CSI), to lispro (administered by CSI) and compared to NOVOLOG® injections and NPH injection. Overall, the reduction in HbA1c was similar to the comparator.

14.2 Clinical Studies in Adult and Pediatric Patients with Type 1 Diabetes with Subcutaneous Injections

Type 1 Diabetes—Adults (see Table 3)

Two 24-week, open-label, active-controlled studies were conducted to compare to meals and regular human insulin was administered by subcutaneous injection in adult patients with type 1 diabetes. Because the two study designs and results were similar, data are shown for only one study (Table 3).

The mean age of the trial population was 39 years and mean duration of diabetes was 15.7 years. Fifty-one percent were male. Ninety-four percent were Caucasian, 2% were Black and 4% were Other. The mean BMI was approximately 25.6 kg/m². NOVOLOG® was administered by subcutaneous injection immediately prior to meals and regular human insulin was administered by subcutaneous injection 30 minutes before meals. NPH insulin was administered as the basal insulin in either single or divided daily doses. Changes in HbA1c were comparable for the two treatment regimens in this study (Table 3).

Table 3. Type 1 Diabetes Mellitus—Adult (NOVOLOG® plus NPH insulin vs. regular human insulin plus NPH insulin)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Baseline HbA1c (%)</th>
<th>24 Weeks</th>
<th>48 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Therapy</td>
<td>7.9 ± 1.1</td>
<td>6.7 ± 1.2</td>
<td>6.6 ± 1.0</td>
</tr>
<tr>
<td>NOVOLOG®</td>
<td>7.8 ± 1.2</td>
<td>6.7 ± 1.2</td>
<td>6.6 ± 1.0</td>
</tr>
<tr>
<td>NPH Insulin Plus NPH Insulin</td>
<td>7.9 ± 1.1</td>
<td>6.7 ± 1.2</td>
<td>6.6 ± 1.0</td>
</tr>
</tbody>
</table>

*Values are Mean ± SD

Type 1 Diabetes—Pediatric (see Table 4)

The efficacy of NOVOLOG® to improve glycemic control in pediatric patients with type 1 diabetes mellitus is based on an adequate and well-controlled trial of regular human insulin in pediatric patients with type 1 diabetes mellitus (Table 4). This 24-week, parallel-group study of pediatric patients with type 1 diabetes (n=283), aged 6 to 18 years, compared two subcutaneous multiple-dose regimen regimens (NOVOLOG® (n=167) or regular human insulin (n=116)). NPH insulin was administered as the basal insulin. Similar effects on HbA1c were observed in both treatment groups (Table 4).

Table 4. Pediatric Subcutaneous Administration of NOVOLOG® in Type 1 Diabetes (24 weeks; n=283)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Baseline HbA1c (%)</th>
<th>24 Weeks</th>
<th>48 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Therapy</td>
<td>7.9 ± 1.1</td>
<td>6.7 ± 1.2</td>
<td>6.6 ± 1.0</td>
</tr>
<tr>
<td>NOVOLOG®</td>
<td>7.8 ± 1.2</td>
<td>6.7 ± 1.2</td>
<td>6.6 ± 1.0</td>
</tr>
<tr>
<td>NPH Insulin Plus NPH Insulin</td>
<td>7.9 ± 1.1</td>
<td>6.7 ± 1.2</td>
<td>6.6 ± 1.0</td>
</tr>
</tbody>
</table>

*Values are Mean ± SD

Type 2 Diabetes—Adults (see Table 5)

Oral formulations, open-label, active-controlled studies were conducted to compare to meals and regular human insulin was administered by subcutaneous injection 30 minutes before meals. NPH insulin was administered as the basal insulin in either single or divided daily doses. Changes in HbA1c were comparable for the two treatment regimens.

Table 5. Type 2 Diabetes Mellitus—Adults (NOVOLOG® plus NPH insulin vs. regular human insulin plus NPH insulin)

<table>
<thead>
<tr>
<th>Treatment</th>
<th>Baseline HbA1c (%)</th>
<th>24 Weeks</th>
<th>48 Weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>No Therapy</td>
<td>7.9 ± 1.1</td>
<td>6.7 ± 1.2</td>
<td>6.6 ± 1.0</td>
</tr>
<tr>
<td>NOVOLOG®</td>
<td>7.8 ± 1.2</td>
<td>6.7 ± 1.2</td>
<td>6.6 ± 1.0</td>
</tr>
<tr>
<td>NPH Insulin Plus NPH Insulin</td>
<td>7.9 ± 1.1</td>
<td>6.7 ± 1.2</td>
<td>6.6 ± 1.0</td>
</tr>
</tbody>
</table>

*Values are Mean ± SD
Table 5. Subcutaneous NOVOLOG® Administration in Type 2 Diabetes (6 months; n=176)

<table>
<thead>
<tr>
<th>NOVOLOG®+</th>
<th>Regular Human Insulin +</th>
<th>PNP</th>
</tr>
</thead>
<tbody>
<tr>
<td>NPH (n=59)</td>
<td>NPH (n=58)</td>
<td></td>
</tr>
<tr>
<td>Baseline HbA1c (%)</td>
<td>7.3 ± 0.7</td>
<td>7.5 ± 0.8</td>
</tr>
<tr>
<td>Change from Baseline HbA1c (%)</td>
<td>0.0 ± 0.2</td>
<td>0.2 ± 0.6</td>
</tr>
<tr>
<td>Treatment Difference in HbA1c, Mean (95% confidence interval)</td>
<td>-0.1 (-0.1, 0.4)</td>
<td></td>
</tr>
</tbody>
</table>

*Values are Mean ± SD

Table 6. Adult Insulin Pump Study in Type 1 Diabetes (16 weeks; n=118)

<table>
<thead>
<tr>
<th>NOVOLOG®</th>
<th>Buffed human insulin (n=59)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline HbA1c (%)</td>
<td>7.3 ± 0.7</td>
</tr>
<tr>
<td>Change from Baseline HbA1c (%)</td>
<td>0.0 ± 0.2</td>
</tr>
<tr>
<td>Treatment Difference in HbA1c, Mean (95% confidence interval)</td>
<td>-0.1 (-0.1, 0.4)</td>
</tr>
</tbody>
</table>

*Values are Mean ± SD

Table 7. Pediatric Insulin Pump Study in Type 1 Diabetes (16 weeks; n=298)

<table>
<thead>
<tr>
<th>NOVOLOG® (n=198)</th>
<th>Insulin lispro (n=100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline HbA1c (%)</td>
<td>6.0 ± 0.2</td>
</tr>
<tr>
<td>Change from Baseline HbA1c (%)</td>
<td>-0.1 ± 0.8</td>
</tr>
<tr>
<td>Treatment Difference in HbA1c, Mean (95% confidence interval)</td>
<td>-0.1 (-0.3, 0.1)</td>
</tr>
</tbody>
</table>

*Values are Mean ± SD

Table 8. Therapy Pump in Type 2 Diabetes (16 weeks; n=127)

<table>
<thead>
<tr>
<th>NOVOLOG® pump (n=66)</th>
<th>NOVOLOG® + NPH (n=61)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline HbA1c (%)</td>
<td>8.2 ± 1.4</td>
</tr>
<tr>
<td>Change from Baseline HbA1c (%)</td>
<td>-0.6 ± 1.5</td>
</tr>
<tr>
<td>Treatment Difference in HbA1c, Mean (95% confidence interval)</td>
<td>-0.1 (0.3, 0.4)</td>
</tr>
</tbody>
</table>

*Values are Mean ± SD

16.2 Recommended Storage

Dispense in the original sealed carton with the enclosed instructions for Use. Store unused NOVOLOG® in a refrigerator between 2°C to 8°C (36°F to 46°F). Do not freeze NOVOLOG® and do not use NOVOLOG® if it has been frozen. Do not expose NOVOLOG® to excessive heat or light. Do not withdraw NOVOLOG® into a syringe and store for later use. Always remove and discard the needle after each injection from the NOVOLOG® FlexPen® or NOVOLOG® FlexTouch® and store without a needle attached.

The storage conditions are summarized in the following table:

Table 9. Storage Conditions for vial, PenFill® cartridges, NOVOLOG® FlexPen®, and NOVOLOG® FlexTouch®

<table>
<thead>
<tr>
<th>NOVOLOG® presentation</th>
<th>Not-in-use (unopened)</th>
<th>Not-in-use (unopened) Refrigerated (2°C to 8°C)</th>
<th>In-use (opened) Room Temperature (above 30°C)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 mL multiple-dose vial</td>
<td>Until expiration date</td>
<td>28 days* (refrigerated/room temperature)</td>
<td>28 days* (room temperature)</td>
</tr>
<tr>
<td>3 mL single-patient-use PenFill® cartridges</td>
<td>Until expiration date</td>
<td>28 days (Do not refrigerate)</td>
<td>28 days (Do not refrigerate)</td>
</tr>
<tr>
<td>3 mL single-patient-use FlexPen®</td>
<td>Until expiration date</td>
<td>28 days (Do not refrigerate)</td>
<td>28 days (Do not refrigerate)</td>
</tr>
<tr>
<td>3 mL single-patient-use FlexTouch®</td>
<td>Until expiration date</td>
<td>28 days (Do not refrigerate)</td>
<td>28 days (Do not refrigerate)</td>
</tr>
</tbody>
</table>

*For insulin pump use, the total in-use time is 19 days, including 7 days pump in-use time.

Storage in External Insulin Pump

Change the NOVOLOG® in the pump reservoir at least every 7 days or, according to the pump user manual, whichever is shorter, or after exposure to temperatures that exceed 37°C (98.6°F).

Storage of Diluted NOVOLOG®

NOVOLOG® diluted with Insulin Diluting Medium for NOVOLOG® to a concentration equivalent to U-100 or equivalent to U-50 prepared as indicated under Dosage and Administration may remain in patient use at temperatures up to 30°C (86°F) for 28 days.

Storage of NOVOLOG® in Intravenous Infusion Fluids

Infusion bags prepared as indicated under Dosage and Administration (2.2) are stable at room temperature for 24 hours. Some insulin will be initially adsorbed to the material of the infusion.

17.1 Patient Counseling Information

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

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 NOVOLOG® 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). 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). Hypersensitivity Reactions

Inform patients that hypersensitivity reactions have occurred with NOVOLOG®. Inform patients of the symptoms of hypersensitivity reactions (See Warnings and Precautions).

Patients Using Continuous Subcutaneous Insulin Pumps

• Train patients in both intensive insulin therapy with multiple injections and in the function of their pump and pump accessories.

• This NOVOLOG® product can be used with continuous subcutaneous insulin infusion pumps labeled for use with NOVOLOG® (insulin aspart) - refer to the insulin pump user manual to see if NOVOLOG® can be used. See recommended insulin sets in the insulin pump user manual.

• Instruct patients to replace insulin in the reservoir at least every 7 days or according to the user manual, whichever is shorter; infusion sets and infusion set insertion sites should be changed according to the manufacturer’s user manual. By following this schedule, patients avoid insulin degradation, infusion set occlusion, and loss of the insulin preservative.

• Instruct patients to discard insulin exposed to temperatures higher than 37°C (98.6°F).

• Instruct patients to inform physician and select a new site for infusion if infusion site becomes erythematous, pruritic, or thickened.

• Instruct patients of the risk of hyperglycemia and ketosis due to pump malfunction, infusion set occlusion, leakage, disconnection or kinking, and degraded insulin. If these problems cannot be promptly corrected, instruct patients to resume therapy with subcutaneous insulin injection and contact their physician (See Warnings and Precautions). (5.3). How Supplied/Storage and Handling (16.2)

• Instruct patients of the risk of hypoglycemia from pump malfunction. If these problems cannot be promptly corrected, instruct patients to resume therapy with subcutaneous insulin injection and contact their physician (See Warnings and Precautions) (5.3). How Supplied/Storage and Handling (16.2).

Rx only

Manufactured by: Novo Nordisk Inc.
800 Scudders Mill Road
Plainsboro, NJ 08536
1-800-727-6500
U.S. License Number 1261
Version: 30
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For additional information about NOVOLOG®, contact: Novo Nordisk Inc.
600 Scudders Mill Road
Plainsboro, NJ 08536
1-800-727-6500
(Se Habla español)
www.novonordisk-us.com
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US3NL0006 3/2023
PATIENT INFORMATION
NovoLog® (NÔ-vô-log)
(insulin aspart) injection, for subcutaneous or intravenous use

Do not share your NovoLog®, FlexPen®, NovoLog® FlexTouch®, PenFill® cartridge or PenFill® cartridge compatible insulin delivery device 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 NovoLog®?
NovoLog® is a man-made insulin that is used to control high blood sugar in adults and children with diabetes mellitus.

Who should not take NovoLog®?
Do not take NovoLog® if you:
- are having an episode of low blood sugar (hypoglycemia).
- have an allergy to NovoLog® or any of the ingredients in NovoLog®.

Before taking NovoLog®, tell your healthcare provider about all your medical conditions including, if you are:
- pregnant, planning to become pregnant, or are breastfeeding.
- taking new prescription or over-the-counter medicines, vitamins, or herbal supplements.

Before you start taking NovoLog®, talk to your healthcare provider about low blood sugar and how to manage it.

How should I take NovoLog®?
- Read the Instructions for Use that come with your NovoLog®.
- Take NovoLog® exactly as your healthcare provider tells you to.
- NovoLog® starts acting fast. You should eat a meal within 5 to 10 minutes after you take your dose of NovoLog®.
- Know the type and strength of insulin you take. Do not change the type of insulin you take 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 take different types of insulin.
- Check your blood sugar levels. Ask your healthcare provider what your blood sugars should be and when you should check your blood sugar levels.
- 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.
- NovoLog® can be injected under the skin (subcutaneously) of your stomach area (abdomen), buttocks, upper legs (thighs) or upper arms, or by continuous infusion under the skin (subcutaneously) through an insulin pump into an area of your body recommended in the instructions that come with your insulin pump.
- Change (rotate) your injection sites 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.

What should I avoid while taking NovoLog®?
While taking NovoLog® do not:
- Drive or operate heavy machinery, until you know how NovoLog® affects you.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

What are the possible side effects of NovoLog®?
NovoLog® may cause serious side effects that can lead to death, including:
- Low blood sugar (hypoglycemia). Signs and symptoms that may indicate low blood sugar include:
  - dizziness or light-headedness
  - sweating
  - confusion
  - headache
  - blurred vision
  - slurred speech
  - shakiness
  - fast heart beat
  - anxiety, irritability, or mood changes
  - hunger

Your insulin dose may need to change because of:
- change in level of physical activity or exercise
- weight gain or loss
- increased stress
- illness
- change in diet

Other common side effects of NovoLog® may include:
- low potassium in your blood (hypokalemia), reactions at the injection site, itching, rash, serious allergic reactions (whole body reactions), skin thickening or pits at the injection site (lipodystrophy), weight gain, and swelling of your hands and feet.

Get emergency medical help if you have:
- trouble breathing, shortness of breath, fast heartbeat, swelling of your face, tongue, or throat, sweating, extreme drowsiness, dizziness, confusion.

These are not all the possible side effects of NovoLog®. 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 NovoLog®.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. You can ask your pharmacist or healthcare provider for information about NovoLog® that is written for health professionals. Do not use NovoLog® for a condition for which it was not prescribed. Do not give NovoLog® to other people, even if they have the same symptoms that you have. It may harm them.

What are the ingredients in NovoLog®?
Active Ingredient: insulin aspart
Inactive Ingredients: disodium hydrogen phosphate dihydrate, glycerin, metacresol, phenol, sodium chloride, zinc, and Water for Injection, USP. Hydrochloric acid 10% and/or sodium hydroxide 10% may be added to adjust pH.
Manufactured by: Novo Nordisk Inc., Plainsboro, NJ 08536 U.S. License Number 1261
For more information, go to www.novonordisk-us.com or call 1-800-727-6500.

This Patient Information has been approved by the U.S. Food and Drug Administration.
Revised: 02/2023
INSTRUCTIONS FOR USE
NovoLog® (N0-vo-log) (insulin aspart) injection, for subcutaneous or intravenous use
10 mL multiple-dose vial (100 Units/mL, U-100)

Read this Instructions for Use before you start taking NovoLog® and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

Supplies you will need to give your NovoLog® injection:
• 10 mL NovoLog® vial
• insulin syringe and needle
• alcohol swabs

Preparing your NovoLog® dose:
• Wash your hands with soap and water.
• Before you start to prepare your injection, check the NovoLog® label to make sure that you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.
• NovoLog® should look clear and colorless. Do not use NovoLog® if it is thick, cloudy, or is colored.
• Do not use NovoLog® past the expiration date printed on the label.

Step 1: Pull off the tamper resistant cap (See Figure A).

Step 2: Wipe the rubber stopper with an alcohol swab (See Figure B).

Step 3: Hold the syringe with the needle pointing up. Pull down on the plunger until the black tip reaches the line for the number of units for your prescribed dose (See Figure C).

Step 4: Push the needle through the rubber stopper of the NovoLog® vial (See Figure D).

Step 5: Push the plunger all the way in. This puts air into the NovoLog® vial (See Figure E).

Step 6: Turn the NovoLog® vial and syringe upside down and slowly pull the plunger down until the black tip is a few units past the line for your dose (See Figure F).

Step 7: Slowly push the plunger up until the black tip reaches the line for your NovoLog® dose (See Figure G).

Step 8: Check the syringe to make sure you have the right dose of NovoLog®.

Step 9: Pull the syringe out of the vial’s rubber stopper (See Figure I).

Giving your Injection:
• Inject your NovoLog® exactly as your healthcare provider has shown you. Your healthcare provider should tell you if you need to pinch the skin before injecting.
• NovoLog® can be injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs or upper arms, infused in an insulin pump (continuous subcutaneous infusion into an area of your body recommended in the instructions that come with your insulin pump), or through a given through a needle in your arm (intravenously) by your healthcare provider.
• If you inject NovoLog®, 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.
• If you use NovoLog® in an insulin pump, you should change your infusion set and insertion site according to the manufacturer’s user manual. NovoLog® should be given into an area of your body recommended in the instructions that come with your insulin pump. Change (rotate) your insertion sites within the area you choose for each insulin injection 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 into 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. The insulin in the reservoir should be changed at least every 7 days or according to the pump user manual, whichever is shorter, even if you have not used all of the insulin.
• If you use NovoLog® in an insulin pump, see your insulin pump manual for instructions or talk to your healthcare provider.
• NPH insulin is the only type of insulin that can be mixed with NovoLog®. Do not mix NovoLog® with any other type of insulin.
• NovoLog® should only be mixed with NPH insulin if it is going to be injected right away under your skin (subcutaneously).
• NovoLog® should be drawn up into the syringe before you draw up your NPH insulin.
• Talk to your healthcare provider if you are not sure about the right way to mix NovoLog® and NPH insulin.

Step 10: Choose your injection site (stomach area, buttocks, upper legs or upper arms) and wipe the skin with an alcohol swab. Let the injection site dry before you inject your dose (See Figure J).

Step 11: Insert the needle into your skin. Push down on the plunger to inject your dose (See Figure K). The needle should remain in the skin for at least 6 seconds to make sure you have injected all the insulin.

Step 12: Pull the needle out of your skin. After that, you may see a drip of NovoLog® at the needle tip. This is normal and does not affect the dose you just received (See Figure L).
• 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 swab. Do not rub the area.

After your injection:
• Do not recap the needle. Recapping the needle can lead to a needle stick injury.
• Put the empty insulin vials, used needles and syringes in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and syringes and 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, and 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 the 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.

How should I store NovoLog®?
• Do not freeze NovoLog®. Do not use NovoLog® if it has been frozen.
• Keep NovoLog® away from heat or light.
• All unopened vials:
  • Store unopened NovoLog® 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 28 days, if they are stored at room temperature.

• After vials have been opened:
  • Opened NovoLog® vials can be stored in the refrigerator at 36°F to 46°F (2°C to 8°C) or at room temperature below 86°F (30°C).
  • Throw away all opened NovoLog® vials after 28 days, even if they still have insulin left in them.
  • If using NovoLog® in a pump, throw away all opened NovoLog® vials after 19 days.

General information about the safe and effective use of NovoLog®
• Always use a new syringe and needle for each injection.
• Do not share syringes or needles.
• Keep NovoLog® vials, syringes, and needles out of the reach of children.
INSTRUCTIONS FOR USE

NovoLog® (Novo-vo-log) (insulin aspart) injection, for subcutaneous or intravenous use
3 mL FlexPen® prefilled pen (100 units/mL, U-100)

Introduction
Please read the following instructions carefully before using your NovoLog® FlexPen®.

Do not share your NovoLog® 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.

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

People who are blind or have vision problems should not use this Pen without help from a person trained to use the Pen.

Getting ready
Make sure you have the following items:
• NovoLog® FlexPen®
• New NovoFine®, NovoFine® Plus or NovoTwist® needle
• Alcohol swabs

NovoLog® FlexPen®

Rubber stopper
Cartridge scale
Protection tab
Push-button selector

NovoFine® Big outer needle cap
NovoFine® Plus Big outer needle cap
NovoTwist® Big outer needle cap

Preparing your NovoLog® 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. NovoLog® should look clear and colorless.

Do not use your NovoLog® FlexPen® if the liquid contains particles or is colored.

A. Pull off the pen cap (see diagram A).
B. Wipe the rubber stopper with an alcohol swab.

C. Pull off the big outer needle cap (see diagram C).
D. Pull off the inner needle cap and throw it away (dispose of it) (see diagram D).

E. Turn the dose selector to select 2 units (see diagram E).
F. Hold your NovoLog® 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 F).

G. Keep the needle pointing upwards, press the push-button all the way in (see diagram G). 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 NovoLog® FlexPen® and contact Novo Nordisk at 1-800-727-6500.

H. 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 H). When turning the dose selector, be careful not to press the button on the FlexPen® 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. Do not set the dose by counting the number of clicks you hear because you may get an incorrect dose.

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

Giving the injection
Do 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.

NovoLog® 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 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.

I. 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 I). Be careful only to push the button when injecting. Turning the dose selector will not inject insulin.

J. 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 J). 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 an alcohol swab. Do not rub the area.

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

After the injection
Do not recap the needle. Recapping can lead to a needle stick injury. Remove the needle from the NovoLog® 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.

• 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, and
  • 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 the 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 NovoLog® FlexPen® for your prescribed dose, the NovoLog® FlexPen® may be thrown away in your household trash after you have removed the needle.

The NovoLog® FlexPen® prevents the cartridge from being completely emptied. It is designed to deliver 300 units.

K. Put the pen cap on the NovoLog® FlexPen® and store the NovoLog® FlexPen® without the needle attached (see diagram K). Storing without the needle attached helps prevent leaking, blocking of the needle, and air from entering the Pen.

How should I store NovoLog® FlexPen®?

- Do not freeze NovoLog®. Do not use NovoLog® if it has been frozen.
- Keep NovoLog® away from heat or light.
- Store the NovoLog® FlexPen® without the needle attached.

Until first use:
- Store unused NovoLog® FlexPen® in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Unused FlexPen® may be used until the expiration date printed on the label, if kept in the refrigerator.
- Unused NovoLog® FlexPen® stored at room temperature should be thrown away after 28 days.

In-use:
- Store the FlexPen® you are currently using out of the refrigerator at room temperature below 86°F (30°C) for up to 28 days.
- The NovoLog® FlexPen® you are using should be thrown away after 28 days, even if it still has insulin left in it.

Maintenance

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

- Remove the needle from the NovoLog® 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 NovoLog® FlexPen® and needles out of the reach of children.
- Use NovoLog® FlexPen® as directed to treat your diabetes.
- Do not share your NovoLog® 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 NovoLog® FlexPen® is lost or damaged.
- Remember to keep the disposable NovoLog® FlexPen® with you. Do not leave it in a car or other location where it can get too hot or too cold.
**INSTRUCTIONS FOR USE**

**NovoLog® (N-o-v-o-log)** (insulin aspart) injection, for subcutaneous or intravenous use

3 mL FlexTouch® prefilled pen (100 units/mL, U-100)

- Do not share your NovoLog® FlexTouch® Pen 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.

- NovoLog® FlexTouch® Pen (“Pen”) is a prefilled, single-patient-use disposable pen containing 300 units of U-100 NovoLog® (insulin aspart) injection insulin. You can inject from 1 to 80 units in a single injection. The units can be increased by 1 unit at a time.

- People who are blind or have vision problems should not use this Pen without help from a person trained to use the Pen.

**Supplies you will need to give your NovoLog® injection:**

- NovoLog® FlexTouch® Pen
- a new NovoFine®, NovoFine® Plus or NovoTwist® needle
- alcohol swabs
- 1 sharps container for throwing away used Pens and needles.

**See “Disposing of used NovoLog® FlexTouch® Pens and needles” at the end of these instructions.**

**Preparing your NovoLog® FlexTouch® Pen:**

- Wash your hands with soap and water.

- Before you start to prepare your injection, check the NovoLog® FlexTouch® Pen label to make sure you are taking the right type of insulin. This is especially important if you take more than 1 type of insulin.

- NovoLog® should look clear and colorless. Do not use NovoLog® if it is thick, cloudy, or is colored.

- Do not use NovoLog® past the expiration date printed on the label or 28 days after you start using the Pen.

**Always use a new needle for each injection to make sure the needle is free of germs (sterile) and to 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.**

**NovoFine®**

- Outer needle cap
- Inner needle cap
- Needle
- Paper tab

- Inner needle cap
- Needle
- Paper tab

- Inner needle cap
- Needle
- Paper tab

**Step 1:**

- Pull Pen cap straight off (See Figure B).

**NovoFine® Plus**

**Step 2:**

- Check the liquid in the Pen (See Figure C). NovoLog® should look clear and colorless. Do not use it if it looks cloudy or colored.

**NovoTwist®**

**Step 3:**

- Select a new needle.
- Pull off the paper tab from the outer needle cap (See Figure D).

**Step 4:**

- Push the capped needle straight onto the Pen and twist the needle on until it is tight (See Figure E).

**Step 5:**

- Pull off the outer needle cap. Do not throw it away (See Figure F).

**Step 6:**

- Pull off the inner needle cap and throw it away (See Figure G).

**Step 8:**

- Hold the Pen with the needle pointing up. Tap the top of the Pen gently a few times to let any air bubbles rise to the top (See Figure I).

**Step 9:**

- Hold the Pen with the needle pointing up. Press and hold in the dose button until the dose counter shows “0.” The “0” must line up with the dose pointer.

- A drop of insulin should be seen at the needle tip (See Figure J).

- If you do not see a drop of insulin, repeat steps 7 to 9, no more than 6 times.

- If you still do not see a drop of insulin, change the needle and repeat steps 7 to 9.

**Selecting your dose:**

**Step 10:**

- Turn the dose selector to select the number of units you need to inject. The dose pointer should line up with your dose (See Figure K).

- If you select the wrong dose, you can turn the dose selector forwards or backwards to the correct dose.

- The even numbers are printed on the dial.

- The odd numbers are shown as lines.

- The NovoLog® FlexTouch® Pen insulin scale will show you how much insulin is left in your Pen (See Figure L).

**Step 7:**

- Turn the dose selector to select 2 units (See Figure H).

- The dose pointer will line up with the number of units of insulin that is left in your Pen. If the dose counter shows 80, there are at least 80 units left in your Pen.

- If the dose counter shows less than 80, the number shown in the dose counter is the number of units left in your Pen.
Giving your injection:

• Inject your NovoLog® exactly as your healthcare provider has shown you. Your healthcare provider should tell you if you need to pinch the skin before injecting.

• NovoLog® can be injected under the skin (subcutaneously) of your stomach area (abdomen), 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. For each injection, change (rotate) your injection site within the area of skin that you use. 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.

Step 11:

• Choose your injection site and wipe the skin with an alcohol swab. Let the injection site dry before you inject your dose (See Figure M).

• Insert the needle into your skin (See Figure N).

Make sure you can see the dose counter. Do not cover it with your fingers, this can stop your injection.

Step 12:

• Press and hold down the dose button until the dose counter shows “0” (See Figure O).

• The “0” must line up with the dose pointer. You may then hear or feel a click.

• Keep the needle in your skin after the dose counter has returned to “0” and slowly count to 6 (See Figure P).

When the dose counter returns to “0”, you will not get your full dose until 6 seconds later.

• If the needle is removed before you count to 6, you may see a stream of insulin coming from the needle tip.

• If you see a stream of insulin coming from the needle tip you will not get your full dose. If this happens you should check your blood sugar levels more often because you may need more insulin.

Step 13:

• Pull the needle out of your skin (See Figure Q).

• 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 swab. Do not rub the area.

Step 14:

• Carefully remove the needle from the Pen and throw it away (See Figure R).

• Do not recap the needle. Recapping the needle can lead to needle stick injury.

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

• Do not store the Pen with the needle attached. Storing without the needle attached helps prevent leaking, blocking of the needle, and air from entering the Pen.

Step 15:

• Replace the Pen cap by turning it clockwise (See Figure T).

• Until first use:

• Store unused NovoLog® FlexTouch® Pens in the refrigerator at 36°F to 46°F (2°C to 8°C).

• Unused Pens 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 NovoLog® FlexTouch® Pen stored at room temperature should be thrown away after 28 days.

• In-use:

• Store the Pen you are currently using out of the refrigerator at room temperature below 86°F.

• The NovoLog® FlexTouch® Pen you are using should be thrown away after 28 days, even if it still has insulin left in it.

General Information about the safe and effective use of NovoLog®

• Keep NovoLog® FlexTouch® Pens and needles out of the reach of children.

• Always use a new needle for each injection.

• Do not share your NovoLog® FlexTouch® Pens or needles with other people. You may give other people a serious infection, or get a serious infection from them.

How should I store my NovoLog® FlexTouch® Pen?

• Do not freeze NovoLog®. Do not use NovoLog® if it has been frozen.

• Keep NovoLog® away from heat or light.

• Store the NovoLog® FlexTouch® Pen without the needle attached.

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

Manufactured by:
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Plainsboro, NJ 08536
U.S. License Number 1261
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INSTRUCTIONS FOR USE
NovoLog® (Novo-vo-log®) (insulin aspart) injection, for subcutaneous or intravenous use
PenFill® 3 mL cartridge 100 units/mL (U-100)

• Do not share your PenFill® cartridge or PenFill® cartridge compatible insulin delivery device 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.
• Your healthcare provider should show you or your caregiver how to inject NovoLog® the right way before you inject it for the first time.
• NovoLog® PenFill® cartridge 100 units/mL is a prefilled, single-patient-use cartridge containing 300 units of NovoLog® (insulin aspart).
• After you insert the PenFill® cartridge in your device, you can use it for multiple injections. Read the instruction manual that comes with your insulin delivery device for complete instructions on how to use the PenFill® cartridge with the device.
• People who are blind or have vision problems should not use this PenFill® cartridge without help from a person trained to use the PenFill® cartridge with the device.
• If using a new NovoLog® PenFill® cartridge, start with Step 1.
• If the NovoLog® PenFill® cartridge has already been used, start with Step 2.

Supplies you will need to give your NovoLog® injection:
• NovoLog® PenFill® cartridge
• Novo Nordisk 3 mL PenFill® cartridge compatible insulin delivery device
• 1 new NovoFine®, NovoFine® Plus, or NovoTwist® needle
• Alcohol swabs
• Adhesive bandage
• Cotton gauze
• A sharp container for throwing away used PenFill® cartridges and needles. See “After your injection” at the end of these instructions.

NovoFine®
Outer needle cap
Inner needle cap
Needle
Paper tab

NovoFine® Plus
Outer needle cap
Inner needle cap
Needle
Paper tab

NovoTwist®
Outer needle cap
Inner needle cap
Needle
Paper tab

PenFill® cartridge compatible insulin delivery device
Cartridge holder
Dose counter
Dose selector/dose button
Pen cap
Dose pointer
Colored band
Rubber plunger

PenFill® cartridge 3 mL (example)

Threaded end (for needle attachment)

How to use the NovoLog® PenFill® cartridge
• Wash your hands with soap and water.
• Before you start to prepare your injection, check the NovoLog® PenFill® cartridge label to make sure that it contains the insulin you need. This is especially important if you take more than 1 type of insulin.
• The tamper-resistant foil should be in place before the first use. If the foil has been broken or removed before your first use of the cartridge, do not use it. Call Novo Nordisk at 1-800-727-6500.
• Carefully look at the cartridge and the insulin inside it. Check that the NovoLog® cartridge:
  • is not damaged, for example cracked or leaking
  • is not loose on the threaded end
• NovoLog® should look clear and colorless.
Do not use NovoLog® if it is cloudy or colored or if the threaded end is loose (See Figure B).

Step 1:
• Insert a 3 mL cartridge with the threaded end first into your Novo Nordisk 3 mL PenFill® cartridge compatible insulin delivery device (See Figure C).
• If you drop your device, check the insulin cartridge for damage such as cracks or leaking. If your cartridge is damaged, throw it away and use a new one.

Prepare your device with a new needle
Step 2:
• Take a new needle, and tear off the paper tab. Always use a new needle for each injection to make sure the needle is free of germs (sterile) and to prevent blocked needles. Do not attach a new needle to your device until you are ready to give your injection. Do not reuse or share your needles with other people. You may give others a serious infection, or get a serious infection from them.
• Be careful not to bend or damage the needle before you use it.
• Push the needle straight onto the device. Turn the needle clockwise until it is on tight (See Figure D).

Step 3:
• Pull off the outer needle cap and throw it away (See Figure E). Do not try to put the inner needle cap back on the needle.

Step 4:
• Pull off the inner needle cap and throw it away (See Figure F). Do not try to put the inner needle cap back on the needle.

A drop of insulin may appear at the needle tip. This is normal, but you must still check the insulin flow.

Check the insulin flow
Step 5:
• Small amounts of air may collect in the cartridge during normal use. You must do an airshot before each injection to avoid injecting air and to make sure you receive the prescribed dose of your medicine.
• Do the airshot as described in the instruction manual that comes with your device.
• Keep testing your Novo Nordisk 3 mL PenFill® cartridge compatible insulin delivery device until you see insulin at the needle tip. If you still do not see a drop of insulin after 6 times, change the needle and repeat this step. This makes sure that any air bubbles are removed and that insulin is getting through the needle (See Figure G).

Select your dose
Step 6:
• Check to make sure that the dose counter is set to 0.
• Turn the dose selector clockwise to select the dose you need to inject (See Figure H). The pointer should line up with your dose. When turning the dose selector, be careful not to press the dose button as insulin will come out. You will hear a click for every single unit dialed. Do not set the dose by counting the number of clicks you hear because you may get an incorrect dose.
• Refer to your insulin delivery device manual if necessary.

Inject your dose
Step 2:
• Do 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.
• NovoLog® can be injected under the skin (subcutaneously) of your stomach area (abdomen), buttocks, upper legs (thighs), or upper arms (See Figure I).
• 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.
• Clean your injection site with an alcohol swab. Let your skin dry. Do not touch this area again before injecting.
• Insert the needle into your skin. Press and hold down the dose button until the dose counter shows “0”. Continue to keep the dose button pressed and keep the needle in your skin and slowly count to 6 (see Figure J).
NovoLog® (insulin aspart) injection PenFill®

How should I store my NovoLog® PenFill® cartridge?

- Do not freeze NovoLog®. Do not use NovoLog® if it has been frozen.
- Keep NovoLog® away from heat or light.
- Store the NovoLog® PenFill® cartridge without the needle attached.

Before use:
- Store unused NovoLog® PenFill® cartridges in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Unused PenFill® cartridges may be used until the expiration date printed on the label, if kept in the refrigerator.
- If NovoLog® is stored mistakenly outside of refrigeration between 47°F (9°C) to 86°F (30°C) prior to first use, it should be used within 28 days or thrown away.

PenFill® cartridges in use:
- Store the PenFill® cartridge you are currently using in the insulin delivery device at room temperature below 86°F (30°C) for up to 28 days. Do not refrigerate.
- The NovoLog® PenFill® cartridge you are using should be thrown away after 28 days, even if it still has insulin left in it.

General Information about the safe and effective use of NovoLog®.
- Keep NovoLog® PenFill® cartridges and needles out of the reach of children.
- Do not share NovoLog® PenFill® cartridges or needles with other people. You may give other people a serious infection, or get a serious infection from them.
- Always carry extra insulin of the same type(s) you use in case of loss or damage.

Before you inject

- Remove the needle from your skin.
- You may see a drop of NovoLog® at the needle tip after injecting. 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 cotton gauze and cover with an adhesive bandage, if necessary. Do not rub the area.

After your injection

Step 8:
- Lay your outer needle cap on a flat surface.
- Carefully, lead the needle tip into the outer needle cap without touching the needle. (See Figure K) and push the outer needle cap completely on.
- Hold the black cartridge holder on the insulin delivery device and unscrew the needle counterclockwise (See Figure L).
- Throw away (dispose of) the needle in an FDA-cleared sharps container as your healthcare professional has instructed you.
- Put your empty NovoLog® PenFill® cartridge and used needles in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and PenFill® cartridges 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, and
  - leak-resistant and 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. Do not reuse or share your needles or syringes with other people. For more information about the 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.

Step 9:
- Keep the 3 mL PenFill® cartridge in the device. Do not store your device with a needle attached. This will prevent infection or leakage of insulin and will make sure that you receive the right dose of NovoLog®.
- Put the pen cap on your device after each use to protect the insulin from light (See Figure M).

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

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