insulin aspart injection 100 Units/mL

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

--- RECENT MAJOR CHANGES ---
Dosage and Administration (2.1) 12/2018
Dosage and Administration (2.2) 11/2019
Warnings and Precautions (2.5) 11/2019

--- INDICATIONS AND USAGE ---

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

Dosage and Administration (2.1)

See Full Prescribing Information for important 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 Insulation (Insulin Pump) (2.2):
- 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.
- Change the NOVOLOG® in the reservoir at least every 6 days.
- Change the infusion set and the infusion set insertion site at least every 3 days.
- 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.
- 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 ---
Each presentation contains 100 Units of insulin aspart per mL (U-100)
- 10 mL multiple-dose vial (3)
- 3 mL single-patient-use PenFill® cartridges for the 3 mL PenFill® cartridge device (3)
- 3 mL single-patient-use NOVOLOG® FlexPen® (3)
- 3 mL single-patient-use NOVOLOG® FlexTouch® (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).

Hyperglycemia or hypoglycemia with changes in insulin regimen: Make changes to a patient’s insulin regimen (e.g., insulin strength, manufacturer, type, injection site or method of administration) under close medical supervision with increased frequency of blood glucose monitoring (5.2).

Hypoglycemia: May be life-threatening. Increase frequency of glucose monitoring with changes to insulin dosage, co-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: anti-diabetic agents, ACE inhibitors, angiotensin II receptor blocking agents, diisopropramide, furosime, monoamine oxidase inhibitors, pentoxyfilline, propranolol, propyphenoxine, 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, glaucagon, isoniazid, niacin, oral contraceptives, phenothiazines, progestogens (e.g., in 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).

--- USE IN SPECIFIC POPULATIONS ---
Pediatric: Has not been studied in children with type 2 diabetes. Has not been studied in children with type 1 diabetes <2 years of age (6.4).

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

Revised: 11/2019

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2.5 Instructions for Mixing with Other Insulins

2.5.1 Continuous Subcutaneous Infusion Subcutaneous Injection

Intravenous Administration

Insulin aspart (NovoLog®) is a rapid-acting human insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus.

2.2 Route of Administration

2.1 Important Administration Instructions

2.2 Route of Administration

Continuous Subcutaneous Infusion (Insulin Pump)

2.3 Dosage Information

Dosage adjustment may be needed when switching from another insulin to NovoLog® (see Warnings and Precautions [5.1]).

2.4 Drug Interaction

Adapted from the original text. Full text is available upon request.
Similar incidences. These antibodies did not cause deterioration in glycemic control or severe hypoglycemia, and their effect was reversible with drug discontinuation.

6.3 Post Marketing Experience

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

Medication errors have been reported in which other insulins have been confused with repeated injections into areas of localized cutaneous amyloidosis, hypoglycemia has been reported with repeated injections into areas of localized cutaneous amyloidosis, hypoglycemia has been reported with repeated injection into an area of localized cutaneous amyloidosis, and hypoglycemia has been reported with repeated injection into an area of localized cutaneous amyloidosis.

7. DRUG INTERACTIONS

**Drugs that May Increase the Risk of Hypoglycemia**

- Anti-diabetic agents
- AACE inhibitors
- Arginine II receptor blocking agents, disopyramide, fribates, fluoxetine, monamine oxidase inhibitors, pentoxifylline, pramlintide, propoxyphene, salicylates, statin antagonist (e.g., ezetimibe), and sulfonamide antibiotics.

**Intervention:** Dose adjustment and increased frequency of glucose monitoring may be required when NOVOLOG® is co-administered with these drugs.

**Drugs that May Decrease the Blood Glucose Lowering Effect of NOVOLOG®**

- Hypoglycemic agents
- Alpha-2 adrenergic agents, clonidine, guanethidine, and reserpine.

**Intervention:** Dose adjustment and increased frequency of glucose monitoring may be required when NOVOLOG® is co-administered with these drugs.

**Drugs that May Increase or Decrease the Blood Glucose Lowering Effect of NOVOLOG®**

- Alcohol, beta-blockers, clonidine, and lithium salts.
- Pentamidine.
- Propranolol.
- Albendazole.
- Corticosteroids, danazol, diuretics, estrogens, glucagon, sympathomimetic agents (e.g., ephedrine), thalidomide, and tolbutamide.

**Intervention:** Dose adjustment and increased frequency of glucose monitoring may be required when NOVOLOG® is co-administered with these drugs.

**Drugs that May Blunt Signs and Symptoms of Hypoglycemia**

- Beta-blockers, clonidine, guanethidine, and reserpine.

**Intervention:** Increased frequency of glucose monitoring may be required when NOVOLOG® is co-administered with these drugs.

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 insulin aspart and major birth defects or adverse maternal or fetal outcomes. However, insulin dose, intensity of glucose control, and baseline metabolic control may contribute to adverse outcomes. Intensification or rapid improvement in glucose control has been associated with an increased risk of hypoglycemia and hypokalemia, and may sometimes be followed by hyperglycemia.

**Intervention:** Dose adjustment and increased frequency of glucose monitoring may be required when NOVOLOG® is co-administered with these drugs.

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 at concentrations similar to those observed in 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

NOVOLOG® is approved for use in children for subcutaneous daily injections of subcutaneous continuous infusion by external insulin pump (see Clinical Studies (14.1, 14.2)). NOVOLOG® has not been studied in pediatric patients younger than 2 years of age. NOVOLOG® has not been studied in pediatric patients with type 2 diabetes.

8.5 Geriatric Use

The total number of patients (n=375) treated with NOVOLOG® in 3 controlled clinical studies, 2.6% (n=36) were 65 years of age or over. One-half of these patients had type 1 diabetes (18/285) and the other half had type 2 diabetes (18/80). The HbA1c response to NOVOLOG®, as compared with 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 (see Warnings and Precautions (5.3, 5.6)). Mild episodes of hypoglycemia usually can be treated with oral glucose. Adjustments in drug dosage, meal patterns, or both may be needed. More severe episodes with coma, seizure, or neurologic impairment may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous glucose. Sustained carbohydrate intake and observation may be necessary because hypoglycemia may recur after apparent clinical recovery. Hypokalemia must be corrected appropriately.

11. DESCRIPTION

NOVOLOG® (insulin aspart injection) is a rapid-acting human insulin analog used to lower blood glucose. NOVOLOG® is homologous with human insulin and contains the exception of a single substitution of the amino acid proline by aspartic acid in position B28. It is produced by recombinant DNA technology utilizing Saccharomyces cerevisiae (baker’s yeast). Insulin aspart has the empirical formula C381S and a molecular weight of 6282.

Figure 1. Structural formula of insulin aspart.

**Table 2: Adverse reactions occurring in ≥5% of Type 2 Diabetes Mellitus Patients in Phase 3 TITAN and/or TITAN+ trials. NOVOLOG® was compared to insulin aspart at the same rate or greater on NOVOLOG® than on comparator**

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>Insulin aspart (n=235)</th>
<th>NOVOLOG® + NPH (%) (n=91)</th>
<th>Human Regular Insulin + NPH (%) (n=91)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hypoglycemia</td>
<td>11</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Nephrolithiasis</td>
<td>10</td>
<td>5</td>
<td>5</td>
</tr>
<tr>
<td>Sensory disturbance</td>
<td>9</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>8</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Chest pain</td>
<td>5</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Headache</td>
<td>5</td>
<td>3</td>
<td>3</td>
</tr>
<tr>
<td>Skin disorder</td>
<td>5</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>5</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Sinusitis</td>
<td>5</td>
<td>1</td>
<td>1</td>
</tr>
</tbody>
</table>

*NOVOLOG® (insulin aspart injection) is a rapid-acting human insulin analog used to lower blood glucose. NOVOLOG® is homologous with human insulin and contains the exception of a single substitution of the amino acid proline by aspartic acid in position B28. It is produced by recombinant DNA technology utilizing Saccharomyces cerevisiae (baker’s yeast). Insulin aspart has the empirical formula C381S and a molecular weight of 6282.*
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 protein synthesis, and enhances protein synthesis.

12.2 Pharmacodynamics
Subcutaneous administration
The pharmacodynamic profile of NOVOLOG® given subcutaneously in 27 patients with type 1 diabetes is shown in Figure 2. The maximum glucose-lowering effect of NOVOLOG® occurred between 1 and 3 hours after subcutaneous injection (0.15 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]).

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.

Intravenous administration
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). Mean Blood Glucose (mg/dL)

Note: The slashes on the mean profile indicate a jump on the time axis.

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.

12.3 Pharmacokinetics
Subcutaneous administration
Absorption and Bioavailability
In studies in healthy volunteers (total n=187) and patients with type 1 diabetes (total n=40), the median time to maximum concentration of NOVOLOG® in these trials was 40 to 50 minutes versus 80 to 120 minutes, for regular human insulin respectively.

The relative bioavailability of NOVOLOG® (0.15 units/kg) compared to regular human insulin indicates that the two insulins are absorbed to a similar extent. In a clinical trial in patients with type 1 diabetes, NOVOLOG® and regular human insulin, both administered subcutaneously at a dose of 0.15 units/kg body weight, reached mean maximum concentrations of 62 and 36 mcU/ml, respectively.

Distribution
Insulin aspart has a low binding affinity to plasma proteins (<10%), similar to that seen with regular human insulin.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Standard 2-year carcinogenicity studies in animals have not been performed to evaluate the carcinogenic potential of NOVOLOG®. In 52-week Sprague-Dawley rats and Sprague-Dawley rats dosed subcutaneously with NOVOLOG® at 10, 50, and 200 units/kg/day (approximately 2, 8, and 32 times the human subcutaneous dose of 1.0 unit/kg/day, based on units/body surface area 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. NOVOLOG® was not genotoxic in the following tests: Ames test, mouse lymphoma cell forward gene mutation test, human peripheral blood lymphocyte chromosomal aberration test, in vivo micronucleus test in mice, and in vivo two UDS 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 a radiomimetic, double-blind, crossover study 17 healthy Caucasian male subjects between 16 and 40 years of age received an intravenous infusion of either NOVOLOG® or regular human insulin at 1.5 mU/kg/min for 120 minutes. The mean insulin clearance was similar for the two groups with a mean clearance of 0.15 L/min/kg for the NOVOLOG® group and 1.2 L/min/kg for the regular human insulin group.

After subcutaneous administration in normal male volunteers (n=24), NOVOLOG® was eliminated with an apparent equal half-life of 81 minutes.

Species Populations
Pediatrics - The pharmacokinetic and pharmacodynamic properties of NOVOLOG® and regular human insulin were evaluated in a single dose study in 18 children (6-12 years, n=9) and adolescents (13-17 years, Tanner grade ≥ 2, n=9) with type 1 diabetes. The relative differences in pharmacokinetics and pharmacodynamics in children and adolescents with type 1 diabetes between NOVOLOG® and regular human insulin were similar to those in healthy adult subjects and adults with type 1 diabetes.

Geriatrics - The pharmacokinetic and pharmacodynamic properties of NOVOLOG® and regular human insulin were evaluated in a single dose study in 18 subjects with type 2 diabetes who were ≥ 65 years of age. The relative differences in pharmacokinetics and pharmacodynamics in geriatric patients with type 2 diabetes between NOVOLOG® and regular human insulin were comparable to those in younger adults.

Gender - In healthy volunteers given a single subcutaneous dose of NOVOLOG® 0.06 units/kg, no difference in insulin aspart levels was seen between men and women based on comparison of AUC(0-90 min) or Cmax. Observations from subcutaneous administrations of NOVOLOG® 0.15 units/kg were administered in a study of 23 patients with type 1 diabetes and a wide range of body mass index (BMI), 22-39 kg/m². The pharmacokinetic parameters, AUC and Cmax, of NOVOLOG® were generally unaffected by BMI (N=23) within this range.

The efficacy of NOVOLOG® to improve glycemic control in pediatric patients with type 1 diabetes mellitus is based on in vitro and in vivo pharmacodynamic studies and on clinical trials of regular human insulin in pediatric patients with type 1 diabetes melitus (Table 4). This 24-week, parallel-group study of children and adolescents with type 1 diabetes (n=283), aged 6 to 18 years, compared NOVOLOG® + NPH insulin to NPH insulin alone. The efficacy and safety of NOVOLOG® in pediatric patients (n=157) was similar to those in type 2 diabetes mellitus patients (Table 5). Subcutaneous administration of NOVOLOG® and regular human insulin have also been compared with type 1 diabetes (n=26) aged 2 to 6 years with similar effects on HbA1c.

14.1 Overview of Clinical Studies
The safety and effectiveness of subcutaneous NOVOLOG® was compared to regular human insulin in 536 type 1 diabetes adult, 187 pediatric type 1 diabetes, and 91 adult type 2 diabetes patients using NPH as basal insulin (see Tables 3, 4, 5). The reduction in glycosylated 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 CGI and CSII) and to regular human insulin injection. Overall, the reduction in HbA1c was similar to the comparator.

14.2 Clinical Studies in Adult and Pediatric Patients with Type 1 Diabetes and Subcutaneous Daily Injections
Type 1 Diabetes – Adults (see Table 3)
Two 24-week, open-label, active-controlled studies were conducted to compare the safety and efficacy of NOVOLOG® to regular human insulin injection in adult patients with type 1 diabetes. Because the two study designs and results were similar, data are shown for only one study (see Table 3).

The mean age of the trial population was 38.9 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 25.8 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 considered when switching from one insulin to another or from divided daily doses to a single daily dose administration of NPH or regular human insulin. Similar effects on HbA1c were observed in both treatment groups (Table 5).

Subcutaneous administration of NOVOLOG® and regular human insulin have also been compared in children with type 1 diabetes (n=26) aged 2 to 6 years with similar effects on HbA1c.

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

Type 1 Diabetes – Pediatrics (see Table 4)

The efficacy of NOVOLOG® to improve glycemic control in pediatric patients with type 1 diabetes mellitus is based on in vitro and in vivo pharmacodynamic studies and on clinical trials of regular human insulin in pediatric patients with type 1 diabetes melitus (Table 4). This 24-week, parallel-group study of children and adolescents with type 1 diabetes (n=283), aged 6 to 18 years, compared NOVOLOG® + NPH insulin to NPH insulin alone. The efficacy and safety of NOVOLOG® in pediatric patients (n=157) was similar to those in type 2 diabetes mellitus patients (Table 5). Subcutaneous administration of NOVOLOG® and regular human insulin have also been compared with type 1 diabetes (n=26) aged 2 to 6 years with similar effects on HbA1c.

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

Type 2 Diabetes – Adults (see Table 5)
One six-month, open-label, active-controlled study was conducted to compare the safety and efficacy of NOVOLOG® to regular human insulin in patients with type 2 diabetes (Table 5). The mean age of the trial population was 56.6 years and mean duration of diabetes was 12.7 years. Sixty-three percent were male. Seventy-six percent were Caucasian, 9% were Black and 15% were Other. The mean BMI was approximately 32.7 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.

Table 5. Subcutaneous NOVOLOG® Administration in Type 2 Diabetes (6 months; n=576)

14.3 Clinical Studies in Adults with Type 2 Diabetes and Subcutaneous Daily Injections
Type 2 Diabetes – Adults (see Table 5)

14 CLINICAL STUDIES

In standard biological assays in mice and rabbits, one unit of NOVOLOG® has the same glucose-lowering effect as one unit of regular human insulin.
14.4 Clinical Studies in Adults and Pediatrics with Type 1 Diabetes Using Continuous Subcutaneous Insulin Infusion (CSII) by External Pump

Type 1 Diabetes – Adults (see Table 6)

Two open-label, parallel design studies (6 weeks [n=29] and 16 weeks [n=118]) compared NOVOLOG® to buffered regular human insulin (Velsulin) in adults with type 1 diabetes receiving a subcutaneous infusion with an external insulin pump. The mean age of the trial population was 42.3 years. Thirty-nine percent were male. Ninety-eight percent were Caucasian and 2% were Black. The two treatment regimens had comparable changes in HbA\textsubscript{1c}.

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

<table>
<thead>
<tr>
<th>NOVOLOG® (N=59)</th>
<th>Buffered human insulin (N=59)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline HbA\textsubscript{1c} (%)</td>
<td>7.3 ± 0.7</td>
</tr>
<tr>
<td>Change from Baseline HbA\textsubscript{1c} (%)</td>
<td>0.0 ± 0.5</td>
</tr>
<tr>
<td>Treatment Difference in HbA\textsubscript{1c}, Mean (95% confidence interval)</td>
<td>0.2 (-0.1, 0.4)</td>
</tr>
</tbody>
</table>

*Values are Mean ± SD

Type 1 Diabetes – Pediatrics (see Table 7)

A randomized, 16-week, open-label, parallel design study of children and adolescents with type 1 diabetes (n=298) aged 4-18 years compared two subcutaneous infusion regimens administered via an external insulin pump. NOVOLOG® (n=198) or insulin lispro (n=100). These two results were reflected in comparable changes in baseline HbA\textsubscript{1c} (Table 8).

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

<table>
<thead>
<tr>
<th>NOVOLOG® (N=198)</th>
<th>Lispro (N=100)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline HbA\textsubscript{1c} (%)</td>
<td>8.0 ± 0.9</td>
</tr>
<tr>
<td>Change from Baseline HbA\textsubscript{1c} (%)</td>
<td>-0.1 ± 0.8</td>
</tr>
<tr>
<td>Treatment Difference in HbA\textsubscript{1c}, Mean (95% confidence interval)</td>
<td>-0.1 (-3.3, 0.1)</td>
</tr>
</tbody>
</table>

*Values are Mean ± SD

14.5 Clinical Studies in Adults with Type 2 Diabetes Using Continuous Subcutaneous Insulin Infusion (CSII) by External Pump

Type 2 Diabetes – Adults (see Table 8)

An open-label, 16-week parallel design trial compared pre-prandial NOVOLOG® injection in conjunction with NPH injections to NOVOLOG® administered by continuous subcutaneous infusion in 127 adults with type 2 diabetes. The mean age of the trial population was 55.1 years. Sixty-four percent were female. Eighty percent were Caucasian, 12% were Black and 8% were Other. The mean BMI was approximately 32.2 kg/m\textsuperscript{2}. The two treatment groups had similar reductions in HbA\textsubscript{1c} (Table 8).

Table 8. Pump Therapy 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 HbA\textsubscript{1c} (%)</td>
<td>8.2 ± 1.4</td>
</tr>
<tr>
<td>Change from Baseline HbA\textsubscript{1c} (%)</td>
<td>-0.6 ± 1.1</td>
</tr>
<tr>
<td>Treatment Difference in HbA\textsubscript{1c}, Mean (95% confidence interval)</td>
<td>0.1 (-3.3, 3.4)</td>
</tr>
</tbody>
</table>

*Values are Mean ± SD

16 HDW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

NOVOLOG® 100 units of insulin aspart per mL (U-100) is available as a clear and colorless solution for injection in:

- 10 mL multiple-dose vial
- 3 mL single-patient-use PenFill® cartridges
- 3 mL single-patient-use FlexPen®
- 3 mL single-patient-use NOVOLOG® FlexTouch®
- 3 mL single-patient-use NOVOLOG® FlexPen®

NOVOLOG® PenFill® cartridges are designed for use with Novo Nordisk insulin delivery devices with NovoFine® disposable needles. FlexPen® and FlexTouch® can be used with NovoFine® or NovoTwist® disposable needles. The NOVOLOG® FlexPen® and FlexTouch® dial in 1-unit increments.

16.2 Recommended Storage

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

Unused NOVOLOG® should be stored in a refrigerator between 2° and 8°C (36° 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. NOVOLOG® should not be drawn into a syringe and stored 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. This prevents contamination and/or infection, or leakage of insulin, and will ensure accurate dosing.

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</th>
<th>In-use opened (below 30°C/86°F)</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mL multiple-dose vial</td>
<td>28 days</td>
<td>Until expiration date</td>
<td>28 days (refrigerated)</td>
</tr>
<tr>
<td>3 mL single-patient-use PenFill® cartridges</td>
<td>28 days</td>
<td>Until expiration date</td>
<td>28 days (refrigerated/room temperature)</td>
</tr>
<tr>
<td>3 mL single-patient-use NOVOLOG® FlexPen®</td>
<td>28 days</td>
<td>Until expiration date</td>
<td>28 days (Do not refrigerate)</td>
</tr>
<tr>
<td>3 mL single-patient-use NOVOLOG® FlexTouch®</td>
<td>28 days</td>
<td>Until expiration date</td>
<td>28 days (Do not refrigerate)</td>
</tr>
</tbody>
</table>

Storage in External Insulin Pump:

NOVOLOG® in the pump reservoir should be discarded after at least every 6 days of use or after exposure to temperatures that exceed 37°C (98.6°F). The infusion set and the infusion set insertion site should be changed at least every 3 days.

Storage of Diluted NOVOLOG®

NOVOLOG® diluted with Insulin Diluting Medium for NOVOLOG® to a concentration equivalent to U-10 to equivalent to U-50 prepared as indicated under Dosage and Administration (2.2) may remain in patient use at temperatures below 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 PATIENT COUNSELING INSTRUCTION

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

Never Share a NOVOLOG® FlexPen® or a NOVOLOG® FlexTouch® Cartridge or PenFill® Cartridge Device Between Patients

Advise patients that they must never share NOVOLOG® FlexPen®, NOVOLOG® FlexTouch®, PenFill® cartridge or PenFill® cartridge devices with another person even if the needle is changed, because doing so carries a risk for transmission of blood-borne pathogens. Advise patients using NOVOLOG® vials not to share needles or syringes with another person. Sharing poses a risk for transmission of blood-borne pathogens (see Warnings and Precautions (5.1)).

Hyperglycemia or Hypoglycemia

Inform patients that hyperglycemia is the most common adverse reaction with insulin. Inform patients on self-management procedures including glucose monitoring, proper injection technique, and management of hyperglycemia and hypoglycemia, especially at initiation of NOVOLOG® therapy. Inform patients on handling of special situations such as incorrect 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. Inform patients on the management of hyperglycemia (see Warnings and Precautions (5.3)).

Inform patients that their ability to concentrate and react may be impaired as a result of hyperglycemia. Advise patients who have frequent hyperglycemia 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 with Medication Errors

Advise patient to always check the insulin label before each injection to avoid mix-ups between insulin products (see Warnings and Precautions (5.3)).

Hypersensitivity Reactions

Advise patients that hypersensitivity reactions have occurred with NOVOLOG®. Inform patients of the symptoms of hypersensitivity reactions (see Warnings and Precautions (5.4)).

Administration

NOVOLOG® must only be used if the solution is clear and colorless with no particles visible. Instruct patients that when injecting NOVOLOG®, they must press and hold down the dose button until the dose counter shows 0 and then keep the needle in the skin and count slowly to 6 as the prescribed dose is not completely delivered until 6 seconds later. If the needle is removed earlier, the full dose may not be delivered (a possible under-dose may occur by as much as 20%). Inform the patient to increase the frequency of checking their blood glucose and that possible additional insulin administration may be necessary.

If the needle does not appear in the dose counter after continuously pressing the dose button, the patient may have used a blocked needle. In this case they would not have received any insulin – even though the dose counter has moved from the original dose that was set. Instruct the patient to change the needle as described in Section 5 of the Instructions for Use and repeat all steps in the EUI starting with Section 1. Prepare your pen with a new needle. Make sure the patient selects the full dose needed.

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.
• Instruct patients to replace insulin in the reservoir at least every 6 days; infusion sets and infusion set insertion sites should be changed at least every 3 days. By following this schedule, patients avoid insulin degradation, infusion set occlusion, and loss of the insulin preservative. NOVOLOG® is recommended for use in any reservoir and infusion sets that are compatible with insulin and the specific pump. Please see recommended reservoir and infusion sets in the pump manual.
• 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 rapid hyperglycemia and ketosis due to insulin delivery, 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) and How Supplied/Storage and Handling (16.2)).

Before using an insulin pump with NOVOLOG®, read the pump label to make sure the pump has been evaluated with NOVOLOG®.
Patient Information
NovoLog® (NŌ-vō-log)
(insulin aspart injection)

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

Your insulin dose may need to change because of:
• change in level of physical activity or exercise
• weight gain or loss

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: glycerin, phenol, metacresol, zinc, disodium hydrogen phosphate dihydrate, sodium chloride and water for injection

Manufactured by:
Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark
For more information, go to www.novonordisk-us.com or call 1-800-727-6500.
Instructions for Use
NovoLog® (Nō-vō-log)
(insulin aspart injection)
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 one type of insulin.
• NovoLog® should look clear and colorless. Do not use NovoLog® if it is thick, cloudy, or 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 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 insertion site every 3 days. 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 insertion to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the insertion sites. Do not insert into the exact same spot for each insertion. Do not insert where the skin has pits, is thickened, or has lumps. Do not insert 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 6 days 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.

Step 10: Choose your injection site 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 drop 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.

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® (N0-vo-log) FlexPen®
(insulin aspart injection)

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®
Pen cap
Rubber stopper
Cartridge
Cartridge scale
Pointer
Dose selector
Push-button

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 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.

Attaching the needle
Remove the protective tab from a disposable needle. Screw the needle tightly onto your FlexPen®. It is important that the needle is put on straight (see diagram B).

NovoFine® NovoFine® Plus NovoTwist®

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).

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.

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 ensure proper dosing:

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 finger 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.

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.

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 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 because you may get an incorrect dose.

I. Insert the needle into your skin.

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.

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 tightly with 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 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®, or your prescribed dose, the NovoLog® FlexPen® may be thrown away in your household trash after you have removed the needle cap.

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

J. 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.
Preparing your NovoLog

Supplies you will need to give your NovoLog injection:

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

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

Preparation of 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.
- Do not use NovoLog® if it is thick, cloudy, or colored.
- Do not use NovoLog® past the expiration date printed on the label or 28 days after you start using the Pen.

Insulin aspart injection (insulin aspart injection) FlexTouch®

Step 1:

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

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.

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 7:

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

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.

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).

To see how much insulin is left in your NovoLog® FlexTouch® Pen:

- Turn the dose selector until it stops. The dose counter 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).

Step 12:
- 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 13:
- 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 14:
- 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 15:
- 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 16:
- Replace the Pen cap by pushing it straight on (See Figure T).

After your injection:
- You can put your used NovoLog® FlexTouch® Pen and needles in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and Pens 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 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 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.

Step 17:
- You can put your used NovoLog® FlexTouch® Pen and needles in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and Pens 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 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 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.

Step 18:
- You can put your used NovoLog® FlexTouch® Pen and needles in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and Pens 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 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 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.

Step 19:
- You can put your used NovoLog® FlexTouch® Pen and needles in a FDA-cleared sharps disposal container right away after use. Do not throw away (dispose of) loose needles and Pens 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 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 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.
Instructions for Use

NovoLog® (N-o-v-o-log) PenFill® 3 mL cartridge
100 Units/mL (U-100) (insulin aspart injection)

- 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 injection) 100 Units/mL insulin.
- 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 Sharps container for throwing away used PenFill® cartridges and needles. See “After your injection” at the end of these instructions.

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 (See Figure E). Do not throw it away. You will need it after the injection to safely remove 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 leg (thigh), 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 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).
• 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 light-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).

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 48°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.