Getting Started on NovoLog® FlexPen®

A discreet, prefilled, dial-a-dose insulin pen

Works with Novo Nordisk pen needles
Prefilled with 300 units of insulin
Large, clear dosing window
Accurate and adjustable dose setting in 1-unit increments
Push-button injection

NovoLog® FlexPen® use
- Never share with anyone, even if you attach a new pen needle
- Use a new pen needle for every injection
- Remove pen needle after every injection and discard into a puncture-resistant container
- Never place a disposable pen needle on NovoLog® FlexPen® until you’re ready to use it
- If NovoLog® FlexPen® isn’t working properly, perform a function check according to the Patient Instructions for Use on back

NovoLog® FlexPen® is about the size of a fountain pen and fits neatly inside a pocket or purse.
And it lasts up to 28 days without refrigeration after first use, so it can be taken almost anywhere.b

NovoLog® FlexPen® use
- Needles are sold separately and may require a prescription in some states. Needles and NovoLog® FlexPen® must not be shared.
- Once in use, NovoLog® FlexPen® must be kept at room temperature below 86°F for up to 28 days.

Detailed guidance is a call, click, or visit away

Novo Nordisk Customer Care
Call 1-800-727-6500 to speak with a customer care representative about NovoLog® FlexPen®

Physician & Pharmacist
Contact your doctor or pharmacist to learn more about NovoLog® FlexPen®

NovoLog® FlexPen® Website
Go to Novolog.com for instructions and a training video on using NovoLog® FlexPen®

Cornerstones4Care®
Support and diabetes management tools built around you. Enroll today to get FREE, personalized diabetes support at Cornerstones4Care.com

Indications and Usage

What is NovoLog® (insulin aspart [rDNA origin] injection)?
- NovoLog® is a man-made insulin used to control high blood sugar in adults and children with diabetes mellitus.

Important Safety Information

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.

Who should not take NovoLog®?
Do not take NovoLog® if:
- your blood sugar is too low (hypoglycemia) or you are allergic to any of its ingredients.

Please see additional Important Safety Information on next page.
Please see accompanying Prescribing Information.
A Guide to Using Your NovoLog® FlexPen®

**Important Safety Information (cont’d)**

*Before taking NovoLog®, tell your health care provider about all your medical conditions including, if you are:*
- pregnant, plan to become pregnant, or are breastfeeding.
- taking new prescription or over-the-counter medicines, including supplements.

**Talk to your health care provider about how to manage low blood sugar.**

**How should I take NovoLog®?**
- Read the Instructions for Use and take exactly as directed.
- NovoLog® is fast-acting. Eat a meal within 5 to 10 minutes after taking it.
- Know the type and strength of your insulin. Do not change your insulin type unless your health care provider tells you to.
- Check your blood sugar levels. Ask your health care provider what your blood sugar levels should be and when you should check them.
- 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.

**What should I avoid while taking NovoLog®?**
- Do not drive or operate heavy machinery, until you know how NovoLog® affects you.
- Do not drink alcohol or use medicines that contain alcohol.

**What are the possible side effects of NovoLog®?**

**Serious side effects can lead to death, including:**
- Low blood sugar. Some signs and symptoms include:
  - anxiety, irritability, mood changes, dizziness, sweating, confusion, and headache.

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

**Other common side effects may include:**
- low potassium in your blood, injection site reactions, itching, rash, serious whole body allergic reactions, skin thickening or pits at the injection site, weight gain, and swelling of your hands and feet and if taken with thiazolidinediones (TZDs) possible heart failure.

**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, or confusion.

Please see additional Important Safety Information on previous page.

Please see accompanying Prescribing Information.
NovoLog®
insulin aspart (rDNA origin) injection

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 [rDNA origin] injection) solution for subcutaneous use
Initial U.S. Approval: 2000

RECENT MAJOR CHANGES
• Warnings and Precautions (5.1) 02/2015

INDICATIONS AND USAGE
• NovoLog® is an insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus (1.1).

DOSE AND ADMINISTRATION
• The dosage of NovoLog® must be individualized.
• Subcutaneous injection: NovoLog® should generally be given immediately (within 5-10 minutes) prior to the start of a meal (2.2).
• Use in pumps: 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. NovoLog® should not be mixed with other insulins or with a diluent when it is used in the pump (2.3).
• Intravenous use: NovoLog® should be used at concentrations from 0.05 U/mL to 1.0 U/mL insulin aspart in infusion systems using polypropylene infusion bags. NovoLog® has been shown to be stable in infusion fluids such as 0.9% sodium chloride (2.4).

DOSE FORMS AND STRENGTHS
Each presentation contains 100 Units of insulin aspart per mL (U-100)
• 10 mL vials (3)
• 3 mL PenFill® cartridges for the 3 mL PenFill® cartridge device (3)
• 3 mL NovoLog® FlexPen® (3)
• 3 mL NovoLog® FlexTouch® (3)

CONTRAINDICATIONS
• Do not use during episodes of hypoglycemia (4).
• Do not use in patients with hypersensitivity to NovoLog® or one of its excipients.

WARNINGS AND PRECAUTIONS
• Never share a NovoLog® FlexPen®, NovoLog® FlexTouch®, PenFill® cartridge, or PenFill® cartridge compatible insulin delivery device between patients, even if the needle is changed (5.1).
• Hypoglycemia is the most common adverse effect of insulin therapy. Glucose monitoring is recommended for all patients with diabetes. Any change of insulin dose should be made cautiously and only under medical supervision (5.2, 5.3).
• Insulin, particularly when given intravenously or in settings of poor glycemic control, can cause hypokalemia. Use caution in patients predisposed to hypokalemia (5.4).
• Like all insulins, NovoLog® requirements may be reduced in patients with renal impairment or hepatic impairment (5.5, 5.6).
• Severe, life-threatening, generalized allergy, including anaphylaxis, may occur with insulin products, including NovoLog® (5.7).
• Fluid retention and heart failure can occur with concomitant use of thiazolidinediones (TZDs), which are PPAR-gamma agonists, and insulin, including NovoLog® (5.11).

ADVERSE REACTIONS
Adverse reactions observed with NovoLog® include hypoglycemia, allergic reactions, local injection site reactions, lipodystrophy, rash and pruritus (6).

DRUG INTERACTIONS
• Drugs that Affect Glucose Metabolism: Adjustment of insulin dosage may be needed (7.1, 7.2, 7.3).
• Anti-Adrenergic Drugs (e.g., beta-blockers, clonidine, guanethidine, and reserpine): Signs and symptoms of hypoglycemia may be reduced or absent (7.3, 7.4).

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 (8.4).

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

Revised: 02/2015

FULL PRESCRIBING INFORMATION: CONTENTS*
1 INDICATIONS AND USAGE
1.1 Treatment of Diabetes Mellitus
2 DOSE AND ADMINISTRATION
2.1 Dosing
2.2 Subcutaneous Injection
2.3 Continuous Subcutaneous Insulin Infusion (CSII) by External Pump
2.4 Intravenous Use
3 DOSE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Never Share a NovoLog® FlexPen®, NovoLog® FlexTouch®, PenFill® Cartridge, or PenFill® Cartridge Compatible Insulin Delivery Device Between Patients
5.2 Administration
5.3 Hypoglycemia
5.4 Hypokalemia
5.5 Renal Impairment
5.6 Hepatic Impairment
5.7 Hypersensitivity and Allergic Reactions
5.8 Antibody Production
5.9 Mixing of Insulins
5.10 Continuous Subcutaneous Insulin Infusion by External Pump
5.11 Fluid retention and heart failure with concomitant use of PPAR-gamma agonists
6 ADVERSE REACTIONS
7 DRUG INTERACTIONS
7.1 Drugs That May Increase the Risk of Hypoglycemia
7.2 Drugs That May Decrease the Blood Glucose Lowering Effect of NovoLog®
7.3 Drugs That May Increase or Decrease the Blood Glucose Lowering Effect of NovoLog®
7.4 Drugs That May Affect Hypoglycemia Signs and Symptoms
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.3 Nursing Mothers
8.4 Pediatric Use
8.5 Geriatric Use
8.6 Gender
8.7 Renal Impairment
8.8 Hepatic Impairment
10 OVERDOSAGE
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics
13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
13.2 Animal Toxicology and/or Pharmacology
14 CLINICAL STUDIES
14.1 Subcutaneous Daily Injections
14.2 Continuous Subcutaneous Insulin Infusion (CSII) by External Pump
14.3 Intravenous Administration of NovoLog®
16 HOW SUPPLIED/STORAGE AND HANDLING
16.1 How Supplied
16.2 Recommended Storage
17 PATIENT COUNSELING INFORMATION
17.1 Never Share a NovoLog® FlexPen®, NovoLog® FlexTouch®, PenFill® Cartridge, or PenFill® Cartridge Device Between Patients
17.2 Physician Instructions
17.3 Patients Using Pumps
17.4 FDA Approved Patient Labeling

*Sections or subsections omitted from the full prescribing information are not listed.
NovoLog® (insulin aspart [rDNA origin] injection)

An insulin analog indicated to improve glycemic control in adults and children with diabetes mellitus.

2 DOSE AND ADMINISTRATION

2.1 Dosing
NovoLog® is an insulin analog with an earlier onset of action than regular human insulin. The dosage of NovoLog® must be individualized. NovoLog® given by subcutaneous injection should generally be used in regimens with an intermediate or long-acting insulin [see Warnings and Precautions (5)]. How Supplied/Storage and Handling (16.2). The total daily insulin requirement may vary and is usually between 0.5 to 1.0 U/kg/day. When used in a meal-related subcutaneous injection treatment regimen, 50 to 70% of total insulin requirements may be provided by NovoLog® and the remainder provided by an intermediate-acting or long-acting insulin. Because NovoLog®'s comparatively rapid onset and short duration of glucose lowering activity, some patients may require more basal insulin and more total insulin to prevent pre-prandial hyperglycemia when using NovoLog® than when using regular human insulin. Do not use NovoLog® that is vaviscous (thickened) or cloudy; use only if it is clear and colorless. NovoLog® should not be used after the printed expiration date.

2.2 Subcutaneous Injection
NovoLog® should be administered by subcutaneous injection in the abdominal region, buttocks, thigh, or upper arm. Because NovoLog® has a more rapid onset and a shorter duration of activity than regular human insulin, it should be injected immediately (within 5-10 minutes) before a meal. Injection sites should be rotated within the same region to distribute and reduce the risk of lipodystrophy. As with all insulins, the duration of action of NovoLog® will vary according to the dose, injection site, blood flow, temperature, and level of physical activity. NovoLog® may be diluted with Insulin Diluting Medium for NovoLog® for subcutaneous injection. Diluting one part NovoLog® to nine parts diluent will yield a concentration one-tenth that of NovoLog® (equivalent to U-50).

2.3 Continuous Subcutaneous Insulin Infusion (CSI) by External Pump
NovoLog® can also be infused subcutaneously by an external insulin pump. How Supplied/Storage and Handling (16.2). How Supplied/Storage and Handling (16.2). Diluted insulin should not be used in external insulin pumps. Because NovoLog® has a more rapid onset and a shorter duration of activity than regular human insulin, premeal boluses of NovoLog® should be infused immediately (within 5-10 minutes) before a meal. Infusion sites should be rotated within the same region to reduce the risk of lipodystrophy. The initial programming of the external infusion pump should be based on the total daily insulin dose of the previous regimen. Although there is significant interpatient variability, approximately 50% of the total dose is usually given as premeal boluses and 50% as basal rates. Some patients may require more basal insulin and more total insulin to prevent hyperglycemia or hypoglycemia.

Change the NovoLog® in the reservoir at least every 6 days, change the infusion sets and the infusion set insertion site at least every 3 days.

The following insulin pumps have been used in NovoLog® clinical or in vitro studies conducted by Novo Nordisk, the manufacturer of NovoLog®:

• Medtronic Paradigm® 512 and 712
• MiniMed 508
• Diepion® D-TRO®7 and H-TRO®

Before using a different insulin pump with NovoLog®, read the pump label to make sure the pump has been evaluated with NovoLog®.

2.4 Intravenous Use
NovoLog® can be administered intravenously under medical supervision for glycemic control with close monitoring of blood glucose and potassium levels to avoid hypoglycemia and hypokalemia [see Warnings and Precautions (5)]. How Supplied/Storage and Handling (16.2). For intravenous use, NovoLog® should be used at concentrations from 0.5 U/mL to 1.0 U/mL insulin aspart in dilution systems, using polysulfone infusion bags. NovoLog® has been shown to be stable in infusion fluids such as 0.9% sodium chloride. Inspect NovoLog® for particulate matter and discoloration prior to parenteral administration.

3 DOSAGE FORMS AND STRENGTHS
NovoLog® is available in the following package sizes: each presentation contains 100 units of insulin aspart per mL (U-100).

• 10 mL vials
• 5 mL NovoLog® cartridges for the 3 mL PenFii® cartridge delivery device (with or without the addition of a NovoPen® 3 PenFii® needle with NovoFine® disposable needles
• 3 mL NovoLog® FlexPen®
• 3 mL NovoLog® FlexTouch®

4 CONTRAINDICATIONS
NovoLog® is contraindicated during episodes of hypoglycemia and in patients with hypersensitivity to NovoLog® or one of its excipients.

5 WARNINGS AND PRECAUTIONS

5.1 Never Share a NovoLog® FlexPen®, NovoLog® FlexTouch®, PenFii®, or PenFii® Cartridge Compatible Device Between Patients
NovoLog® FlexPen®, NovoLog® FlexTouch®, PenFii®, or PenFii® cartridge compatible insulin delivery devices must never be shared between patients, even if the needle is changed. Sharing poses a risk for transmission of blood-borne pathogens.

5.2 Administration
NovoLog® has a more rapid onset of action and a shorter duration of activity than regular human insulin. An injection of NovoLog® should immediately be followed by a meal within 5-10 minutes. Because of NovoLog's short duration of action, a longer acting insulin should also be used in patients with type 1 diabetes when NovoLog® is used alone or when used in conjunction with another insulin. Monitoring is recommended for all patients with diabetes and is particularly important for patients using external pump infusion therapy. Any change of insulin dose should be made cautiously and only under medical supervision. If a new insulin is added to a regimen, the dose of another insulin should be reduced by up to one third to allow sufficient time for the insulin strength may result in the need for a change in dosage. As with all insulin preparations, the time course of NovoLog® action may vary in different individuals or at different times in the same individual and is dependent on many conditions, including temperature, blood flow, and physical activity. Patients who change their level of physical activity or meal plan may require adjustment of insulin dosages. Insulin requirements may be altered during illness, emotional disturbances, or other stresses.

Patients using continuous subcutaneous insulin infusion pump therapy must be trained in insulin infusion and have alternate insulin therapy available in case of pump failure.

5.3 Hypoglycemia
Hypoglycemia is the most common adverse effect of all insulin medications, including NovoLog®. Severe hypoglycemia may lead to unresponsiveness and/or loss of consciousness, cerebral ischemia, or permanent impairment of brain function or death. Severe hypoglycemia requiring assistance of another person and/or parenteral glucose infusion or glucagon administration has been observed in clinical trials with insulin, including trials with NovoLog®.

The timing of hypoglycemia usually reflects the time-action profile of the administered insulin. Clinical Pharmacology (12). Other factors such as changes in food intake (e.g., amount of food or timing of meals), injection site, exercise, and concomitant medications may also alter the risk of hypoglycemia. [see Drug Interactions (7)]. As with all insulin compounds, use caution when administering insulin aspart if you are not familiar with the patient's response to human insulin and in patients who may be predisposed to hypoglycemia (e.g., patients who are fasting or have erratic food intakes). The patient's ability to concentrate and react may be impaired as a result of hypoglycemia. This may present a risk in situations where these abilities are required, for example, when operating machinery. Rapid changes in serum glucose levels may induce symptoms of hypoglycemia in persons with diabetes, regardless of the glucose value. Early warning symptoms of hypoglycemia may be different or less pronounced under certain conditions, such as longstanding diabetes, diabetic nerve disease, use of medications such as beta-blockers, or intensified diabetes control [see Drug Interactions (7)]. These situations may result in severe hypoglycemia (and, possibly, loss of consciousness) prior to the patient's awareness of hypoglycemia. Abnormally administered insulin has a more rapid onset of action than subcutaneously administered insulin, requiring more close monitoring for hypoglycemia.

5.4 Hypokalemia
All insulin products, including NovoLog® have a more rapid onset of action and a shorter duration of activity than subcutaneously administered insulin, particularly when used in combination with insulin. Fluid retention may lead to exacerbate heart failure. Patients treated with insulin, including NovoLog®, and a PPAR-gamma agonist should be observed for signs and symptoms of fluid retention. Blood pressure and edema should be managed according to current standards of care, and discontinuation or dose reduction of the PPAR-gamma agonist must be considered.

6 ADVERSE REACTIONS

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 to those rates reported in another clinical trial, and may not reflect the rates actually observed in clinical practice.

• Hypoglycemia
Hypoglycemia is the most commonly observed adverse reaction in patients using insulin, including NovoLog® [see Warnings and Precautions (5)].

• Hypokalemia
Intensification or rapid improvement in glucose control has been associated with a transitory, reversible ophthalmologic refraction disorder, worsening of diabetic retinopathy, and acute painful peripheral neuropathy. Hypoglycemia can exacerbate heart failure. Patients treated with insulin, including NovoLog®, and a PPAR-gamma agonist should be observed for signs and symptoms of fluid retention. Blood pressure and edema should be managed according to current standards of care, and discontinuation or dose reduction of the PPAR-gamma agonist must be considered.

The following adverse reactions have been reported in clinical trials:

• Superficial pain
• Myalgias
• Fatigue

The following reactions have been reported in post-approval studies:

• Hypoglycemia
• Hypokalemia
• Hypertension
• Peripheral Edema

Insulin may cause sodium retention and edema, particularly in those previously poorly controlled metabolic condition or intensified insulin therapy.

6.1 Fluid retention and heart failure with concomitant use of PPAR-gamma agonists
Thiazolidinediones (TZDs), which are peroxisome proliferator-activated receptor (PPAR)-gamma agonists, can cause dose-dependent fluid retention, particularly when used in combination with insulin. Fluid retention may lead to exacerbate heart failure. Patients treated with insulin, including NovoLog®, and a PPAR-gamma agonist should be observed for signs and symptoms of fluid retention. Blood pressure and edema should be managed according to current standards of care, and discontinuation or dose reduction of the PPAR-gamma agonist must be considered.

6.2 Adverse drug reactions
The frequencies of adverse drug reactions during NovoLog® clinical trials in patients with type 1 diabetes mellitus and type 2 diabetes mellitus are listed in the tables below.
Table 1: Treatment-Emergent Adverse Events in Patients with Type 1 Diabetes Mellitus (Adverse events with frequency ≥ 5% and occurring more frequently with NovoLog® compared to human regular insulin are listed)

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>NovoLog® + NPH N=596</th>
<th>Human Regular Insulin + NPH N=286</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (%)</td>
<td>N (%)</td>
<td></td>
</tr>
</tbody>
</table>

- Hypoglycemia* 25% 26% 33% 36%
- Hypothyroidism 10% 11% 6% 7%
- Diaphoresis 28% 5% 9% 3%

*Hypoglycemia is defined as an episode of blood glucose concentration <8 mg/dL, with or without symptoms. See Section 14 for the incidence of serious hypoglycemia in the individual clinical trials.

Table 2: Treatment-Emergent Adverse Events in Patients with Type 2 Diabetes Mellitus (except for hypoglycemia; adverse events with frequency ≥ 5% and occurring more frequently with NovoLog® compared to human regular insulin are listed)

<table>
<thead>
<tr>
<th>Preferred Term</th>
<th>NovoLog® + NPH N=91</th>
<th>Human Regular Insulin + NPH N=91</th>
</tr>
</thead>
<tbody>
<tr>
<td>N (%)</td>
<td>N (%)</td>
<td></td>
</tr>
</tbody>
</table>

- Hypoglycemia 25% 27% 33% 36%
- Hypereflexia 10% 11% 6% 7%
- Hypothyroidism 10% 9% 5% 5%
- Sensory disturbance 8% 9% 6% 7%
- Urinary tract infection 7% 8% 6% 7%
- Rash 5% 5% 3% 3%
- Pruritus 5% 5% 3% 3%
- Abdominal pain 5% 5% 1% 1%
- Sinusitis 5% 9% 1% 1%

*Hypoglycemia is defined as an episode of blood glucose concentration <8 mg/dL, with or without symptoms. See Section 14 for the incidence of serious hypoglycemia in the individual clinical trials.

Postmarketing Data

The following additional 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. Medication errors in which other insulins have been accidentally substituted for NovoLog® have been identified during post-marketing use (Seeunteresting Information 17).

7. DRUG INTERACTIONS

7.1 Drugs That May Increase the Risk of Hypoglycemia

The risk of hypoglycemia associated with NovoLog® use may be increased with antidiabetic agents, ACE inhibitors, angiotensin II receptor blockers, angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARB), beta-blockers, clonidine, atenolol, beta-adrenergic blocking agents, clonidine, guanosine analogs, high doses of allopurinol, human insulin, sympathetic blocking agents, oral anticoagulants, oral contraceptives, phenothiazines, progestins (e.g., oral contraceptives), prostaglandin inhibitors, somatostatin analogs, and sulfonamide antibiotics. Dose adjustment and increased frequency of glucose monitoring may be required when NovoLog® is co-administered with these drugs.

7.2 Drugs That May Decrease the Blood Glucose Lowering Effect of NovoLog

The glucose lowering effect of NovoLog® may be decreased when co-administered with thyroxin antagonists (e.g., clofibrate and clofibrate), corticosteroids, dexamethasone, estrogens, glucocorticoids, iodinated, niacin, oral contraceptives, phenothiazines, progestins (e.g., oral contraceptives), prostaglandin inhibitors, somatostatin analogs, sympathomimetic agents (e.g., amphetamine, ondansetron, and pindolol). Dose adjustment and increased frequency of glucose monitoring may be required when NovoLog® is co-administered with these drugs.

7.3 Drugs That May Increase or Decrease the Blood Glucose Lowering Effect of NovoLog

The glucose lowering effect of NovoLog® may be increased or decreased when co-administered with alcohol, beta-blockers, clonidine, and lithium salts. Pentamidine may cause hypoglycemia, which may sometimes be followed by hyperglycemia. Dose adjustment and increased frequency of glucose monitoring may be required when NovoLog® is co-administered with these drugs.

7.4 Drugs That May Affect Hypoglycemia Signs and Symptoms

The signs and symptoms of hypoglycemia may be blunted when beta-blockers, clonidine, guanadrel, and reserpine are co-administered with NovoLog®.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category B. All pregnancies have a background risk of birth defects, loss, or other adverse outcome regardless of drug exposure. This background risk is increased in pregnancies complicated by hypoglycemia and may decrease with improved glycemic control. Improved glycemic control is essential for patients with diabetes of history or gestational diabetes to maintain gestational diabetes control before conception and throughout pregnancy. Insulin requirements may decrease during the first trimester, generally increase during the second and third trimesters, and rapidly decline after delivery. Careful monitoring of glucose control is essential in these patients. Therefore, female patients should be advised to tell their physician if they intend to become, or if they become pregnant while taking NovoLog®.

12. PHARMACODYNAMICS

Studies in normal volunteers and patients with diabetes demonstrated that subcutaneous administration of NovoLog® has a more rapid onset and a shorter duration of action than regular human insulin. In a study in patients with type 1 diabetes (n=22), the maximum glucose-lowering effect of NovoLog® occurred between 1 and 3 hours after subcutaneous injection (0.15 U/kg) (see Figure 2). 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 [5.2]).

13. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

The primary activity of NovoLog® is the regulation of glucose metabolism. Insulins, including NovoLog®, bind to the insulin receptors on muscle and fat cells and lower blood glucose by facilitating the cellular uptake of glucose and simultaneously inhibiting the output of glucose from the liver.

12.2 Pharmacokinetics

Absorption - The single-substitution of the amino acid proline with aspartic acid at position B28 in NovoLog® reduces the molecule’s tendency to form hexamers as observed with regular human insulin. NovoLog® is, therefore, more rapidly absorbed after subcutaneous injection compared to regular human insulin (see Figure 4).

The relative bioavailability of NovoLog® (0.15 U/kg) compared to regular human insulin (0.15 U/kg) indicates that the two insulins are absorbed to a similar extent.
8.0 ± 1.1  
104 (17%)  
-0.1 (-0.4, 0.1)  
0.2 (-0.1, 0.4)  
see Indications and Usage (1), Dosage and  
	2  
7.9 ± 1.1  
187  
0.7 ± 0.8  
NovoLog  
-0.5 ± 0.9  
8.0 ± 1.2  
Buffered human insulin  
9 (9%)  
198  
0.7 ± 0.2  
-0.2 (-0.5, 0.1)  
2 (3%)  
0 (0)  
1c  
0.9 ± 0.4  
See Section 12 CLINICAL PHARMACOLOGY  
was not genotoxic in the following tests: Ames test, mouse lymphoma cell  
tumors for NovoLog  
females when compared to untreated controls. The incidence of mammary  
Standard 2-year carcinogenicity studies in animals have not been performed to  
Ethnic origin, pregnancy and smoking on the pharmacokinetics  
there was no correlation between the degree of hepatic impairment and any  
Hepatic Impairment: Some studies with human insulin have shown increased  
Age: Pediatric Population: The pharmacokinetic and pharmacodynamic  
Age: Geriatric Population: The pharmacokinetic and pharmacodynamic  
Age: Pediatric Population: The pharmacokinetic and pharmacodynamic  
and regular human insulin were similar to  
Healthy volunteers given single subcutaneous dose of NovoLog  
19-23 kg/m  
In a randomized, double-blind, crossover study 17 healthy Caucasian male  
and regular human insulin were investigated in a  
Pharmacokinetic parameter.  
Achieved glycemic  
Baseline body weight (kg)*  
*Values are Mean ± SD  
Two six-month, open-label, active-controlled studies were conducted to  
Two six-month, open-label, active-controlled studies were conducted to  
Comparison of changes from baseline:  
**Severe hypoglycemia refers to hypoglycemia associated with central nervous system  
**Severe hypoglycemia refers to hypoglycemia associated with central nervous system  
**Severe hypoglycemia refers to hypoglycemia associated with central nervous system  
Patient with severe hypoglycemia (n, %)*  
Baseline body weight (kg)*  
Weight Change from baseline (kg)*  
*Values are Mean ± SD  
*Values are Mean ± SD  
Tanner grade  
Age of patients in the two treatment groups had similar hyperglycemia  
HbA1c and the incidence rates of severe hypoglycemia  
Table 5. Subcutaneous NovoLog  
Administration in Type 2 Diabetes (6 months; n=176)  
1c  
N  
Baseline body weight (kg)*  
Weight Change from baseline (kg)*  
*Values are Mean ± SD  
*Values are Mean ± SD  
**Severe hypoglycemia refers to hypoglycemia associated with central nervous system  
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**Severe hypoglycemia refers to hypoglycemia associated with central nervous system 
addition of a NovoPen® 3 PenMate®† with NovoFine® disposable needles. FlexPen® and FlexTouch®, can be used with NovoLog®, NovoTwist®, disposable needles. NovoLog®, NovoLog® FlexPen® or FlexTouch® PenFill® cartridge, and PenFill® cartridge compatible insulin delivery devices must never be shared between patients, even if the needle is changed.

16.2 Recommended Storage

Unused NovoLog® should be stored in a refrigerator between 2° and 8°C (36° to 46°F). Do not store in the freezer or directly adjacent to the refrigerator cooling element. Do not freeze NovoLog® and do not use NovoLog® if it has been frozen. NovoLog® should not be drawn into a syringe and stored for later use.

Vials: After initial use a vial may be kept at temperatures below 30°C (86°F) for up to 28 days, but should not be exposed to excessive heat or light. Opened vials may be refrigerated. Unpunctured vials can be used until the expiration date printed on the label if they are stored in a refrigerator. Keep unused vials in the canister so they will stay clean and protected from light.

PenFill® cartridges or NovoLog® FlexPen® and NovoLog® FlexTouch®:

Once a cartridge or NovoLog® FlexPen® or NovoLog® FlexTouch® is punctured, it should be kept at temperatures below 30°C (86°F) for up to 28 days, but should not be exposed to excessive heat or sunlight. A NovoLog® FlexPen® or NovoLog® FlexTouch® or cartridge in use must NOT be stored in the refrigerator. Keep the NovoLog® FlexPen® or NovoLog® FlexTouch® and all PenFill® cartridges away from direct heat and sunlight. Unpunctured NovoLog®, NovoLog® FlexPen®, NovoLog® FlexTouch® and PenFill® cartridges can be used until the expiration date printed on the label if they are stored in a refrigerator. Keep unused NovoLog® FlexPen® or NovoLog® FlexTouch® and PenFill® cartridges in the canister so they will stay clean and protected from light.

Always remove the needle after each injection and store the 3 mL PenFill® cartridge delivery device or NovoLog® FlexPen® or NovoLog® FlexTouch® without a needle attached. This prevents contamination and/or leakage of insulin, and will ensure accurate dosing. Always use a new needle for each injection to prevent contamination.

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.

Summary of Storage Conditions:
The storage conditions are summarized in the following table:

<table>
<thead>
<tr>
<th>NovoLog® presentation</th>
<th>Not-in-use (unopened) Room Temperature (below 30°C)</th>
<th>Not-in-use (unopened) Refrigerated</th>
<th>In-use (opened) Room Temperature (below 30°C)</th>
<th>In-use (opened) Refrigerated</th>
</tr>
</thead>
<tbody>
<tr>
<td>10 mL vial</td>
<td>28 days</td>
<td>Until expiration</td>
<td>28 days (refrigerated/room temperature)</td>
<td>28 days (refrigerated/room temperature)</td>
</tr>
<tr>
<td>3 mL PenFill® cartridges</td>
<td>28 days</td>
<td>Until expiration</td>
<td>28 days (Do not refrigerate)</td>
<td>28 days (Do not refrigerate)</td>
</tr>
<tr>
<td>3 mL NovoLog® FlexPen®</td>
<td>28 days</td>
<td>Until expiration</td>
<td>28 days (Do not refrigerate)</td>
<td>28 days (Do not refrigerate)</td>
</tr>
<tr>
<td>3 mL NovoLog® FlexTouch®</td>
<td>28 days</td>
<td>Until expiration</td>
<td>28 days (Do not refrigerate)</td>
<td>28 days (Do not refrigerate)</td>
</tr>
</tbody>
</table>

Storage of Diluted NovoLog®

NovoLog® diluted with Insulin Diluting Medium for NovoLog® to a concentration equivalent to U-10 or equivalent to U-50 may remain in patient use at temperatures below 30°C (86°F) for 28 days.

Storage of NovoLog® in Infusion Fluids

Infusion bags prepared as indicated under Dosage and Administration (2) are stable at room temperature for 24 hours. Some insulin will be initially adsorbed to the material of the infusion bag.

17.1 Never Share a NovoLog® FlexPen®, NovoLog® FlexTouch®, PenFill® Cartridge, or PenFill® Cartridge Device Between Patients

Advised patients that they must never share a NovoLog® FlexPen®, NovoLog® FlexTouch®, PenFill® cartridge or PenFill® cartridge compatible insulin delivery device with another person, even if the needle is changed, because doing so carries a risk for transmission of blood-borne pathogens.

17.2 Physician Instructions

Maintenance of normal or near-normal glucose control is a treatment goal in diabetes mellitus and has been associated with a reduction in diabetic complications. Patients should be informed about potential risks and benefits of NovoLog® therapy including the possible adverse reactions. Patients should also be offered continued education and advice on insulin therapies, injection technique, life-style management, regular glucose monitoring, periodic glycated hemoglobin testing, recognition and management of hypoglycemia, adherence to meal planning, complications of insulin therapy, timing of dose, instruction in the use of injection or subcutaneous infusion devices, and proper storage of insulin. Patients should be informed that frequent, patient-performed blood glucose measurements are needed to achieve optimal glycemic control and avoid both hypoglycemia and hyperglycemia. Patients should receive proper training on how to use NovoLog®. 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. When the dose counter returns to 0, the prescribed dose is not completely delivered until 6 seconds later. If the needle is removed earlier, they may see a stream of insulin coming from the needle tip. If the full dose will not be delivered (a possible under-dose may occur by as much as 20%), and they should increase the frequency of checking their blood glucose levels and possible additional insulin administration may be necessary.

If the patient did have a blocked needle, instruct them to change the needle as described in Section 5 of the Instructions for Use and re-account all steps in the IPU starting with Section 1. Prepare your pen with a new needle. Make sure the patient selects the full dose needed.

The patient’s ability to concentrate and react may be impaired as a result of hypoglycemia. This may present a risk in situations where these abilities are especially important, such as driving or operating other machinery. Patients who have frequent hypoglycemia or reduced or absent warning signs of hypoglycemia should be advised to use caution when driving or operating machinery.

Accidental substitutions between NovoLog® and other insulin products have been reported. Patients should be instructed to always carefully check that they are administering the appropriate insulin to avoid medication errors between NovoLog® and any other insulin. The written prescription for NovoLog® should be written clearly, to avoid confusion with other insulin products, for example, NovoLog® Mix 70/30.

17.3 Patients Using Pumps

Patients using external pump infusion therapy should be trained in intensive insulin therapy with multiple injections and in the function of their pump and pump accessories.

The following insulin pumps† have been used in NovoLog® clinical or in vitro studies conducted by Novo Nordisk, the manufacturer of NovoLog®:

- Medtronic Paradigm® 752 and 712
- MiniMed 508
- Medtronic D-TRON® and H-TRON®

Before using another insulin pump with NovoLog®, read the pump label to make sure the pump has been evaluated with NovoLog®.

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.

To avoid insulin degradation, infusion set occlusion, and loss of the preservative (metacresol), insulin in the reservoir should be replaced at least every 6 days; infusion sets and infusion set insertion sites should be changed at least every 3 days.

Insulin exposed to temperatures higher than 37°C (98.6°F) should be discarded. The temperature of the insulin may exceed ambient temperature when the pump housing, cover, tubing, or sport case is exposed to sunlight or radiant heat. Infusion sites that are erythematous, pruritic, or thickened should be reported to medical personnel, and a new site selected because continued infusion may increase the skin reaction and/or after the absorption of NovoLog®. Pump or infusion set malfunctions or insulin degradation can lead to hyperglycemia and ketosis in a short time because of the small subcutaneous depot of insulin. This is especially pertinent for rapid-acting insulin analogs that are more rapidly absorbed through skin and have shorter duration of action. These differences are particularly relevant when patients are switched from multiple injection therapy. Prompt identification and correction of the cause of hyperglycemia or ketosis is necessary. Problems include pump malfunction, infusion set occlusion, leakage, disconnection or kinking, and degraded insulin. Less commonly, hypoglycemia from pump malfunction may occur. If these problems cannot be promptly corrected, patients should resume therapy with subcutaneous insulin injection and contact their physician (See Dosage and Administration (2), Warnings and Precautions (5) and How Supplied/Storage and Handling (15.2)).

17.4 FDA Approved Patient Labeling

See separate leaflet.
**Patient Information**

**NovoLog® (NŌ-vō-log)**
(insulin aspart [rDNA origin] injection)

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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.

**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 (rDNA origin)

**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.

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

Revised: 04/2015
Instructions for Use

NovoLog® (NÖ-vō-log)
(insulin aspart [rDNA origin] injection)
10 mL 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 syringes and needle
- alcohol swab

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).
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). 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).

After your injection:
- Do not recap the needle. Recapping the needle can lead to a needle stick injury.
- Throw away empty insulin vials, used syringes, and needles in a sharps container or some type of hard plastic or metal container with a screw on cap such as a detergent bottle or empty coffee can. Check with your healthcare provider about the right way to throw away the container. There may be local or state laws about how to throw away used syringes and needles. Do not throw away used syringes and needles in household trash or recycling bins.

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.
- Store opened and unopened NovoLog® vials in the refrigerator at 36°F to 46°F (2°C to 8°C). Opened NovoLog® vials can also be stored out of the refrigerator below 86°F (30°C).
- Unopened vials may be used until the expiration date printed on the label, if they are kept in the refrigerator.
- Opened NovoLog® vials should be thrown away 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.

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

Revised: March 2013
NovoLog® is a registered trademark of Novo Nordisk A/S.
NovoLog® is covered by US Patent No. 5,866,538 and other patents pending. Manufactured by: Novo Nordisk A/S DK-2880 Bagsvaerd, Denmark
For information about NovoLog® contact: Novo Nordisk Inc. 800 Saunders Mill Road Plainsboro, New Jersey 08536 1-800-727-6500 www.novonordisk-us.com
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Instructions For Use

NovoLog® FlexPen®

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 dia-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.

Never place a disposable needle on your NovoLog® FlexPen® the right way.

Getting ready

Make sure you have the following items:

- NovoLog® FlexPen®
- New NovoFine®, NovoFine® Plus or NovoTwist® needle
- Alcohol swab

NovoLog® FlexPen®

Pen cap

Rubber stopper

Cartridge scale

Pointer

Push-button
dose selector

Big outer needle cap

Inner needle cap

Needle

Protective tab

NovoFine®

Plus

B

C

D

E

F

G

H

I

J

K

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.

A. Pull off the pen cap (see diagram A).

B. 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).

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

D. Pull off the inner needle cap and 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.

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.

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

Never place a disposable needle on your NovoLog® FlexPen® the right way.

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 a finger. 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 NovoLog® FlexPen® 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
  - leak-resistant
  - properly labeled to warn of hazardous waste inside the container
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about 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.

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®?

- Store unused NovoLog® FlexPen® in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Store the FlexPen® you are currently using out of the refrigerator below 86°F (30°C) for up to 28 days.
- Do not freeze NovoLog®. Do not use NovoLog® if it has been frozen.
- Keep NovoLog® away from heat or light.
• Unused FlexPen® may be used until the expiration date printed on the label, if kept in the refrigerator.
• 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.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.
Revised: 04/2015
Read before first use

Instructions for Use
NovoLog® (N-o-v-o-log) FlexTouch® Pen
(insulin aspart [rDNA origin] injection)

- 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 disposable pen containing 300 units of U-100 NovoLog® (insulin aspart [rDNA origin] injection) insulin. You can inject from 1 to 80 units in a single injection.

- This Pen is not recommended for use by the blind or visually impaired without the assistance of a person trained in the proper use of the product.

Supplies you will need to give your NovoLog® injection:
- NovoLog® FlexTouch® Pen
- a new NovoFine®, NovoFine® Plus or NovoTwist® needle
- alcohol swab
- 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 help ensure sterility and prevent blocked needles. Do not reuse or share your needles with other people. You may give other people a serious infection, or get a serious infection from them.

NovoFine®

<table>
<thead>
<tr>
<th>Needle cap</th>
<th>Inner needle cap</th>
<th>Needle</th>
<th>Paper tab</th>
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NovoFine® Plus

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NovoTwist®

<table>
<thead>
<tr>
<th>Needle cap</th>
<th>Inner needle cap</th>
<th>Needle</th>
<th>Paper tab</th>
</tr>
</thead>
</table>

Step 1:
- 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 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:
- Pull 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. 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, and 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 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, and no more than 6 times.
  - If you still do not see a drop of insulin, change the needle and repeat steps 7 to 9.

Examples

- 5 units selected (Figure K)
- 24 units selected (Figure K)
- 50 units selected (Figure K)
- 100 units selected (Figure K)
- 200 units selected (Figure K)

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.
- 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.

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
  - leak-resistant
  - properly labeled to warn of hazardous waste inside the container
- When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. 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?
- Store unused NovoLog® FlexTouch® Pens in the refrigerator at 36°F to 46°F (2°C to 8°C).
- Store the Pen you are currently using out of the refrigerator below 86°F.
- Do not freeze NovoLog®. Do not use NovoLog® if it has been frozen.
- Keep NovoLog® away from heat or light.
- Unused Pens may be used until the expiration date printed on the label, if kept in the refrigerator.
- 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.

Do not throw away (dispose of) loose needles and Pens in your household trash.
Instructions for Use
NovoLog® 3 mL PenFill® 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.

Before using the NovoLog® cartridge
1. Talk with your healthcare provider for information about where to inject NovoLog® (injection sites) and how to give an injection with your insulin delivery device.
2. Read the instruction manual that comes with your insulin delivery device for complete instructions on how to use the PenFill® cartridge with the device.

How to use the NovoLog® cartridge
1. Check your insulin. Just before using your NovoLog® cartridge, check to make sure that you have the right type of insulin. This is especially important if you use different types of insulin.
2. Carefully look at the cartridge and the insulin inside it. The insulin should be clear and colorless. 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, or if the insulin is cloudy or colored, do not use it. Call Novo Nordisk at 1-800-727-6500.
3. Wash your hands well with soap and water. If you clean your injection site with an alcohol swab, let the injection site dry before you inject. Talk with your healthcare provider for guidance on injection sites and how to give an injection with your insulin delivery device.
4. Gather your supplies for injecting NovoLog®.
5. Insert a 3 mL cartridge into your Novo Nordisk 3 mL PenFill® cartridge compatible insulin delivery device. Wipe the front rubber stopper of the 3 mL PenFill® cartridge with an alcohol swab, then attach a new needle. For NovoFine® needles, remove the big outer needle cap and the inner needle cap. Always use a new needle for each injection to prevent infection. 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.

Giving the airshot before each injection:
To prevent the injection of air and to make sure insulin is delivered, you must do an airshot before each injection. Hold the device with the needle pointing up and gently tap the PenFill® cartridge holder with your finger a few times to raise any air bubbles to the top of the cartridge. Do the airshot as described in the device instruction manual.

Giving the injection
6. Dial the number of units on the insulin delivery device that you need to inject. Inject the right way as shown to you by your healthcare provider.
7. Insert the needle into the skin. Inject the dose by pressing the push button all the way in. 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. This will make sure that the full dose has been given. You may see a drop of NovoLog® at the needle tip. This is normal and has no effect on the dose you just received. If blood appears after you take the needle out of your skin, press the injection site lightly with a finger. Do not rub the area.

After the injection
8. Do not recap the needle. Recapping can lead to a needle stick injury.
9. Remove the needle from the PenFill® cartridge after each injection. Keep the 3 mL PenFill® cartridge in the insulin delivery device. The needle should not be attached to the 3 mL PenFill® cartridge during storage. This will prevent infection or leakage of insulin and will help ensure that you receive the right dose of NovoLog®.
10. Put your used NovoLog® PenFill® cartridge and 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
• leak-resistant
• properly labeled to warn of hazardous waste inside the container.
• When your sharps disposal container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you should throw away used needles and syringes. For more information about 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.
11. Put the pen cap back on the Novo Nordisk 3 mL PenFill® cartridge compatible insulin delivery device.