

Information For The Patient
NovoLog[®] (Insulin aspart [rDNA origin] Injection)
3 mL PenFill[®] Disposable Cartridge (300 units per cartridge)
10 mL Vial (1000 units per vial)
100 units/mL (U-100)

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Read this information carefully before you begin treatment. Read the information you get whenever you get more medicine. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment. If you have any questions about NovoLog[®] (NO-voe-log), ask your doctor. Only your doctor can determine if NovoLog[®] is right for you.

What is the most important information I should know about NovoLog?

For All NovoLog Users

- NovoLog (NO-voe-log) is different from regular human insulin and buffered regular human insulin (Velosulin). It works faster (rapid onset of action) and will not work as long (shorter duration of action) as regular human insulin or buffered regular human insulin (Velosulin).
- Because the onset of action is fast, you should eat a meal 5-10 minutes after a NovoLog injection or NovoLog bolus infusion dose given by an external pump. (A bolus is a large dose.) Eating right after the dose will reduce the risk of low blood sugar (hypoglycemia).

- The shorter duration of NovoLog's action means that you may need to use an intermediate or longer-acting insulin (basal insulin) or higher basal rates of NovoLog insulin infusion in the pump. This will give the best glucose control and will help you avoid hyperglycemia (high blood sugar) and ketoacidosis (too much acid [low pH] in your body).
- Glucose monitoring is recommended for all patients who use insulin.

If you use NovoLog by injection, you may need to increase some or all of the following:

- your total dose of insulin
- your dose of intermediate or long-acting insulin (for example, NPH)
- the number of injections of basal insulin

If you infuse NovoLog into the skin (subcutaneous tissue) by pump, you may need to increase some or all of the following:

- your total insulin dose
- the basal infusion dose
- the proportion of total insulin given as a basal infusion

Age and exposure to heat affect the stability of NovoLog and its preservative. Also, NovoLog does not work well after it has been frozen. Therefore, do not use old insulin or insulin that has been exposed to temperature extremes. Hyperglycemia may be a sign that the insulin is no longer working and needs to be replaced.

Do not mix NovoLog:

- with any other insulins when used in a pump
- with Lantus[®] (insulin glargine [rDNA origin] injection) when used with injections by syringe

(You may, however, mix NovoLog with NPH when used with injections by syringe. See: How should I mix insulins?)

For Pump Users

- Glucose monitoring is very important for patients using external pump subcutaneous infusion therapy. You should be aware that pump or infusion set malfunctions that result in inadequate insulin infusion can quickly lead to hyperglycemia and ketosis. Accordingly, problems with the infusion pump, the flow of insulin, or the quality of the insulin should be identified and corrected as quickly as possible. There is only a small amount of insulin infused into the skin with a pump. The faster absorption through the skin of rapid-acting insulin analogs and shorter duration of action may give you less time to identify and correct the problem than with buffered regular insulin.
- Therefore, you should dose with insulin from a new vial of NovoLog if unexplained hyperglycemia or pump alarms do not respond to all of the following:
 - a repeat dose (injection or bolus) of NovoLog
 - a change in the infusion set, including the NovoLog in the reservoir

- a change in the infusion site

If these measures do not work, you may need to resume skin (subcutaneous) injections with syringes or insulin pens. Continue to monitor your glucose and ketones. If problems continue, you must contact your doctor.

- When NovoLog is used in an external subcutaneous insulin infusion pump, you should use only recommended pumps and infusion sets (insulin reservoirs, tubing, catheters). The infusion set, reservoir insulin, and infusion site should be changed:
 - at intervals of 48 hours or less
 - with unexpected hyperglycemia or ketosis
 - when alarms sound, as specified by your MiniMed or Disetronic pump manual
 - if the insulin or pump has been exposed to temperatures over 98.6°F (37°C), as it might be in a sauna, with long showers, or on a hot day
 - if the insulin or pump could have absorbed radiant heat, for example from sunlight, that would heat the insulin to over 98.6°F (37°C). Dark colored pump cases or sport covers can increase this type of heat. The location where the pump is worn may also affect the temperature

Patients who develop “pump bumps” (skin reactions at the infusion site) may need to change infusion sites more often.

For your safety, read the section “What are the possible side effects of NovoLog?” to review the symptoms of low blood sugar (hypoglycemia) and high blood sugar (hyperglycemia).

What is NovoLog?

NovoLog is a clear, colorless, sterile solution for injection or infusion under the skin (subcutaneously). NovoLog is a human-made form of insulin to lower your blood sugar faster than human regular insulin. Because the insulin is human-made by recombinant DNA technology (rDNA) and is chemically different from the insulin made by the human body, it is called an insulin analog. The active ingredient in NovoLog is insulin aspart. The concentration of insulin aspart is 100 units per milliliter, or U100. NovoLog also contains: glycerin, phenol, metacresol, zinc, disodium hydrogen phosphate dihydrate, and sodium chloride. Hydrochloric acid and/or sodium hydroxide may be added to adjust the pH. These ingredients help to preserve or stabilize NovoLog insulin. The pH (balance between acid and alkaline conditions) is important to the stability of NovoLog. Increases in temperature can affect the stability of NovoLog, so it may not work well.

Who should not use NovoLog?

Do not use NovoLog if:

- your blood sugar (glucose) is too low (hypoglycemia)
- you do not plan to eat right after your injection or infusion
- you are allergic to insulin aspart or any of the ingredients contained in NovoLog (check with your doctor if you are not sure)

The effects of NovoLog on an unborn child or on a nursing baby are unknown. Therefore, tell your doctor if you plan to become pregnant or breast feed, or if you become pregnant. You may need to use another medicine.

Tell your doctor about all medicines and supplements that you are using. Some medicines, including non-prescription medicines and dietary supplements, may affect your diabetes.

What should I know about using insulin?

- Make any change of insulin cautiously and only under medical supervision. Changes in the strength, manufacturer, type (for example: Regular, NPH, Lente[®]), species (beef, pork, beef-pork, human) or method of manufacture (recombinant [rDNA] or animal source insulin) may cause a need for a change in the timing or dose of the new insulin.
- Glucose monitoring will help you and your health care provider adjust dosages.
- Always carry a quick source of sugar, such as candy or glucose tablets, to treat low blood sugars (hypoglycemia).
- Always carry identification that states that you have diabetes.

What should I know about using NovoLog?

See the end of this Patient Information for instructions for using NovoLog in injections and pumps.

- NovoLog starts working 10-20 minutes after injection or infusion. The greatest blood sugar lowering effect is between 1 and 3 hours after injection or infusion. This blood sugar lowering lasts for 3 to 5 hours. (The time periods are only general guidelines.)
- Because the onset of action is rapid, you should eat a meal within 5-10 minutes after a NovoLog injection or a NovoLog bolus dose from an external pump to avoid low blood sugar (hypoglycemia).
- The shorter duration of NovoLog's action means that you may need to use an intermediate or longer-acting insulin (basal insulin) or higher basal rates of NovoLog insulin infusion in the pump. This will help you avoid hyperglycemia and ketoacidosis.
- Do not inject or infuse in skin that has become reddened or bumpy or thickened after infusion or injection. Insulin absorption in these areas may not be the same as that in normal skin, and may change the onset and duration of insulin action.
- Use NovoLog only if it appears clear and colorless. Do not use NovoLog if it appears cloudy, thickened, or colored, or if it contains solid particles.

What should I avoid while using NovoLog?

- Drinking alcohol may lead to hypoglycemia.
- Do not miss meals after injections of NovoLog or bolus infusions of NovoLog.

What are the possible side effects of NovoLog?

Insulins can cause hypoglycemia (low blood sugar), hyperglycemia (high blood sugar), allergy, and skin reactions.

Hypoglycemia (insulin reaction). This is the most common side effect. It occurs when there is a conflict between the amount of carbohydrates (source of glucose) from your food, the amount of glucose used by your body, and the amount and timing of insulin dosing. Therefore, **hypoglycemia can occur with:**

- **The wrong insulin dose.** This can happen with any of the following:
 - too much insulin is injected
 - the bolus dose of insulin infusion is set too high
 - the basal infusion dose is set too high
 - the pump does not work right, delivering too much insulin
- **Medicines that directly lower glucose or increase sensitivity to insulin.** This can happen with oral (taken by mouth) antidiabetes drugs, sulfa antibiotics (for infections), ACE inhibitors (for blood pressure and heart failure), salicylates, including aspirin and NSAIDS (for pain), some antidepressants, and with other medicines.
- **Medical conditions that limit the body's glucose reserve, lengthen the time insulin stays in the body, or that increase sensitivity to insulin.** These conditions include diseases of the adrenal glands, the pituitary, the thyroid gland, the liver, and the kidney.
- **Not enough carbohydrate (sugar or starch) intake.** This can happen if:
 - a meal or snack is missed or delayed
 - you have vomiting or diarrhea that decreases the amount of glucose absorbed by your body
 - alcohol interferes with carbohydrate metabolism
- **Too much glucose use by the body.** This can happen from:
 - too much exercise
 - higher than normal metabolism rates due to fever or an overactive thyroid

Hypoglycemia can be mild or severe. Its onset may be rapid. Patients with very good (tight) glucose control, patients with diabetic neuropathy (nerve problems), or patients using some Beta-blockers (used for high blood pressure and heart conditions) may have few warning symptoms before severe hypoglycemia develops. Hypoglycemia may reduce your ability to drive a car or use mechanical equipment without risk of injury to yourself or others. Severe hypoglycemia can cause temporary or permanent harm to your heart or brain. **It may cause unconsciousness, seizures, or death.** Symptoms of hypoglycemia include:

- anxiety, irritability, restlessness, trouble concentrating, personality changes, mood changes, or other abnormal behavior
- tingling in your hands, feet, lips, or tongue
- dizziness, light-headedness, or drowsiness
- nightmares or trouble sleeping

- headache
- blurred vision or slurred speech
- palpitations (rapid heart beat)
- sweating
- tremor (shaking) or unsteady gait (walking)

Mild to moderate hypoglycemia can be treated by eating or drinking carbohydrates (milk, orange juice, sugar candies, or glucose tablets). More severe or continuing hypoglycemia may require the help of another person or emergency medical personnel. Patients who are unable to take sugar by mouth or who are unconscious may need treatment with a glucagon injection or glucose given intravenously (in the vein).

Talk with your doctor about severe, continuing, or frequent hypoglycemia, and hypoglycemia for which you had few warning symptoms.

Hyperglycemia (high blood sugar) is another common side effect. It also occurs when there is a conflict between the amount of carbohydrates (source of glucose) from your food, the amount of glucose used by your body, and the amount and timing of insulin dosing. Therefore, **hyperglycemia can occur with:**

- **The wrong insulin dose.** This can happen from any of the following:
 - too little or no insulin is injected
 - the bolus dose of insulin infusion is set too low
 - the basal infusion dose is set too low
 - the pump or catheter system does not work right, delivering too little insulin
 - the insulin's ability to lower glucose is changed by incorrect storage (freezing, excessive heat), or usage after the expiration date
- **Medicines that directly increase glucose or decrease sensitivity to insulin.** This can happen, for example, with thiazide water pills (used for blood pressure), corticosteroids, birth control pills, and protease inhibitors (used for AIDS).
- **Medical conditions that increase the body's production of glucose or decrease sensitivity to insulin.** These medical conditions include fevers, infections, heart attacks, and stress.
- **Too much carbohydrate intake.** This can happen if you
 - eat larger meals
 - eat more often
 - increase the proportion of carbohydrate in your meals

Hyperglycemia can be mild or severe. It can **progress to diabetic acidosis (DKA) (ketoacidosis) or very high glucose levels (hyperosmolar coma) and result in unconsciousness and death.** Although diabetic acidosis occurs most often in patients with Type 1 diabetes, it can occur in patients with Type 2 diabetes who become severely ill. Urine or blood tests will show acetone, ketones, and high levels of glucose. Hyperosmolar coma occurs most often in patients with Type 2 diabetes. Urine and blood tests will show very high levels of glucose.

Glucose monitoring is very important for patients using external pump infusion therapy. You should be aware that pump or infusion set malfunctions that result in inadequate insulin infusion can quickly lead to hyperglycemia and ketosis. Accordingly, problems with the infusion pump, the flow of insulin, or the quality of the insulin should be identified and corrected as quickly as possible. The faster absorption of rapid-acting insulin analogs through the skin and shorter duration of action may give you less time to identify and correct the problem.

Because some patients experience few symptoms of hyperglycemia and ketosis, it is important to monitor your glucose several times a day. Symptoms of hyperglycemia include:

- confusion or drowsiness
- fruity smelling breath
- rapid, deep breathing
- increased thirst
- decreased appetite, nausea, or vomiting
- abdominal (stomach area) pain
- rapid heart rate
- increased urination and dehydration (too little fluid in your body)

Mild hyperglycemia can be treated by extra doses of insulin and drinking fluids (rehydration). Patients using pumps should check pump function and replace the insulin in the reservoir-syringe, as well as change the tubing and catheter and the infusion site.

Patients using pumps may need to resume insulin injections with syringes or injection pens. Glucose and acetone-ketone levels should be monitored more often until they return to normal. **More severe or continuing hyperglycemia requires prompt evaluation and treatment by your health care provider.**

Allergy can be serious. Generalized allergy is an uncommon, but possibly life-threatening, reaction to insulin products. Symptoms include:

- itchy rash over the entire body
- shortness of breath or wheezing
- confusion
- low blood pressure
- rapid heart beat
- sweating

If you think you are having a generalized allergic reaction, get emergency medical help right away.

Allergic reactions at the injection site (itching, redness, hardness, or swelling) are more common than generalized allergy. They may need several days or weeks to clear up. Pump patients with site reactions may need to change their infusion sites more often than every 48 hours. Patients should avoid injection or infusion of insulin into skin areas that have reactions. Tell your doctor about such reactions, because they can become more severe, or they may change the absorption of insulin.

Lipodystrophy is a common change in the fat below the injection site. These changes include loss of fat (depressions in the skin called lipoatrophy) or thickening of the tissue under the skin (lipohypertrophy). Pump patients with lipodystrophy may need to change their infusion sites more often than every 48 hours. Patients should avoid injection or infusion of insulin into skin areas that have these reactions. Tell your doctor about such reactions because they can become more severe, or they may change the absorption of insulin.

How should I store NovoLog?

- **NovoLog can be damaged by high temperatures.** Therefore, be sure to protect it from high air temperatures, heat from the sun, saunas, long showers, and other heat sources. This is especially important if you use a pump or an insulin pen, because you carry these devices with you and they may be exposed to different temperatures as you go about your daily activities. **Throw NovoLog away if it has been in temperatures greater than 98.6°F (37°C).**
- **Unopened NovoLog** should be stored in a refrigerator but not in the freezer and protected from light. Even if it has been refrigerated and protected from sunlight and unopened, it should not be used after the expiration date on the label and the carton. Unopened vials and cartridges can be stored unrefrigerated at temperatures below 86°F (30°C) and protected from light for up to 28 days.
- **Punctured vials and cartridges** can be stored unrefrigerated at temperatures below 86°F (30°C) and protected from light for up to 28 days. Punctured vials may be stored in the refrigerator. Cartridges inserted into their NovoPen[®] 3 device should not be stored in the refrigerator.
- **The NovoLog in the pump reservoir and the complete infusion set** (reservoir, tubing, catheter-needle) should be replaced **at least every 48 hours**. Replacement should be more often than every 48 hours if you have hyperglycemia, the pump alarm sounds, or the insulin flow is blocked (occlusion).
- Never use NovoLog if it has been stored improperly.

General advice

This leaflet summarizes the most important information about NovoLog. If you would like more information, talk with your doctor. You can ask your pharmacist or doctor for information about NovoLog that is written for health professionals.

Injection and pump infusion instructions

- NovoLog comes in 10 mL (milliliter) vials or in 3 mL cartridges. NovoLog can be withdrawn from vials with syringes for injection or for insertion into the reservoirs of external subcutaneous infusion pumps (Disetronic H-TRON[®] plus V100 or MiniMed Models 505, 506, or 507).

- Doses of insulin are measured in units. NovoLog is available as a U-100 insulin. One milliliter (mL) of U-100 contains 100 units of insulin aspart (1 mL=1 cc). Only U-100 type syringes should be used for injection to ensure proper dosing.
- Disposable syringes and needles are sterile if the package is sealed. They should be used only once and thrown away properly, to protect others from harm.
- NovoLog PenFill[®] cartridges are for use with NovoFine[®] disposable needles and the following 3 mL PenFill[®] compatible delivery devices: NovoPen[®] 3, NovoPen[®] Junior, Innovo[®] and InDuo[™]. Never share needles.

How should I inject NovoLog?

Using Vials

1. The vial and the insulin should be inspected. The insulin should be clear and colorless. The tamper-resistant cap should be in place to be removed by you. If the cap had been removed before your first use of the vial, or if the insulin is cloudy or colored, you should return the vial to the pharmacy. Do not use it.
2. Both the injection site and your hands should be cleaned with soap and water or with alcohol. The injection site should be dry before you inject.
3. The rubber stopper should be wiped with an alcohol wipe.
4. The plunger of the syringe should be pulled back until the black tip is at the level for the number of units to be injected.
5. Insert the needle of the syringe through the rubber stopper of the vial. Push in the syringe plunger completely to put air into the vial.
6. Turn the vial upside-down with the needle-syringe still attached, and pull the plunger back a few units past the correct dose.
7. Remove any air bubbles by flicking the syringe and squirting air bubbles out the needle. Continue pushing the plunger until you have the correct dose.
8. Lift the vial off the syringe.
9. Inject NovoLog into the subcutaneous (under the skin) tissue (not into muscle or blood vessels) in the abdomen, thighs, upper arms, or buttocks. Pinch the skin fold between your fingers and push the needle straight into the pinched skin. Because insulin absorption and activity can be affected by the site you choose, you should discuss the injection site with your doctor.
10. Release the pinched skin and push the plunger in completely. Keep the needle in the skin for a few seconds before withdrawing the syringe.
11. Press the injection site for a few seconds to reduce bleeding. Do not rub.
12. To avoid needle sticks, throw away the syringe and needle without recapping. Discuss sterile technique and proper disposal of your used insulin supplies with your doctor.

Using Cartridges

1. The cartridge and the insulin should be inspected. The insulin should be clear and colorless. The tamper-resistant foil should be in place to be removed by you. If the foil had been punctured or removed before your first use of the cartridge or if the insulin is cloudy or colored, you should return the cartridge to the pharmacy. Do not use it.
2. Both the injection site and your hands should be cleaned with soap and water or with alcohol. The injection site should be dry before you inject. Do not use skin that is reddened, itchy, or thickened as an infusion site.
3. Insert a 3 mL cartridge in the pen-device barrel. Attach a new needle to the end of the cartridge and turn the pen device upside-down so that any air bubbles can be eliminated by flicking the pen device and squirting air bubbles out the needle. (This should eliminate extra air for all future doses from that cartridge. However, the needle will need to be changed for each dose.)
4. Set the dose to be delivered by twisting the top of the pen-device until the correct number appears in the window.
5. Inject NovoLog into the subcutaneous (under the skin) tissue (not into muscle or blood vessels) in the abdomen, thighs, upper arms, or buttocks. Pinch the skin fold between your fingers and push the needle straight into the pinched skin. Because insulin absorption and activity can be affected by the site you choose, you should discuss the injection site with your doctor.
6. Release the pinched skin. Inject the dose by pressing the flat plunger button on the top of the pen-device. Keep the needle in the skin for a few seconds before withdrawing the pen-device.
7. Press the injection site for a few seconds to reduce bleeding. Do not rub.
8. Throw away the disposable needle without recapping to avoid needle sticks. Discuss sterile technique and proper disposal of your used insulin supplies with your doctor.

How should I infuse NovoLog with an external subcutaneous insulin infusion pump?

NovoLog is recommended for use with the Disetronic H-TRON[®] plus V100 and MiniMed 505, 506, and 507 pumps. The Disetronic 3.15 plastic cartridge and Tenders or Classic tubing can be used with the Disetronic pump. The MiniMed 3 mL syringe and Polyfin[®] or Sof-set[®] tubing can be used in the MiniMed pumps. The use of NovoLog in quick-release infusion sets and cartridge adapters has not been assessed.

1. Inspect your insulin as you would for an injection. The insulin should be clear and colorless and without particles. The tamper-resistant cap should be in place to be removed by you. If the cap had been removed before your first use of the vial or if the insulin is cloudy or colored, you should return the vial to the pharmacy. Do not use it.
2. Both the infusion site and your hands should be cleaned with soap and water or with alcohol. The infusion site should be dry before you insert the catheter-needle and tubing. Do not use skin that is reddened, itchy, bumpy or thickened as an infusion site because the onset and duration of NovoLog action may not be the same as that in normal skin.

3. Fill the reservoir-syringe with 2 days worth of NovoLog plus about 25 extra units to prime the pump and fill up the dead space of the infusion tubing.
4. Remove air bubbles from the reservoir according to the pump manufacturers' instructions.
5. Attach the infusion set to the reservoir. Make sure the connection is tight. Prime the infusion set until you see a drop of insulin coming out of the infusion needle-catheter. Flick the tubing to remove air bubbles. Follow the pump manufacturers' instructions for additional priming.
6. Prime the needle-catheter and insert the infusion set into the skin according to the pump manufacturer.
7. Program the pump for mealtime NovoLog boluses and NovoLog basal insulin infusion according to instructions from your doctor and the manufacturer of your pump equipment.
8. Change the infusion site, the insulin reservoir, the tubing, the catheter-needle, and the insulin every 48 hours or less, even if you have not used all of the insulin. This will help ensure that NovoLog and the pump works well. (See "What is the most important information I should know about NovoLog?")
9. Change the infusion site, the insulin reservoir, the tubing, the catheter-needle, and the insulin if you experience a pump alarm, catheter blockage, hyperglycemia, or if your pump insulin has been exposed to heat greater than 98.6°F (37°C). (See "What is the most important information I should know about NovoLog?") Hyperglycemia identified with glucose monitoring may be the first indication of a problem with the pump, infusion set, or NovoLog. Hyperglycemia in the absence of an alarm still requires you to investigate because pump alarms are designed to detect back-pressure and occlusion. The alarms may not detect all the changes to NovoLog that could result in hyperglycemia. You may need to resume subcutaneous insulin injections if the cause of the problem cannot be promptly identified or fixed. (See "Hyperglycemia" under "What are the possible side effects of NovoLog?") Remember that long stretches of tubing increase the risk for kinking and expose the insulin in the tubing to more variations in temperature.

These instructions give you specific information for use of NovoLog in external subcutaneous infusion pumps, but are not a substitute for pump education.

How should I mix insulins?

NovoLog should be mixed only when syringe injections are used. NovoLog can be mixed with NPH human insulin immediately before use. The NovoLog should be drawn into the syringe before the NPH. Mixing with other insulins has not been studied.

NovoLog should not be mixed with Lantus[®] (insulin glargine [rDNA origin] injection). Mixed insulins should NEVER be used in a pump or for intravenous infusion.

1. Add together the doses of NPH and NovoLog. The total dose will determine the final volume in the syringe after drawing up both insulins into the syringe.
2. Roll the NPH vial between your hands until the liquid is equally cloudy throughout.

3. Draw into the syringe the same amount of air as the NPH dose. Inject this air into the NPH vial and then remove the needle without withdrawing or touching any of the NPH insulin. (Transferring NPH to the NovoLog vial will contaminate the NovoLog vial and may change how quickly it works.)
4. Draw into the syringe the same amount of air as the NovoLog dose. Inject this air into the NovoLog vial. With the needle in place, turn the vial upside-down and withdraw the correct dose of NovoLog. The tip of the needle must be in the NovoLog to get the full dose and not an air dose.
5. Insert the needle into the NPH vial. Turn the NPH vial upside down with the syringe-needle still in it. Withdraw the correct dose of NPH.
6. Inject immediately to reduce changes in how quickly the insulin works.

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