

Patient Information

NovoLog[®] (NO-voe-log) (insulin aspart [rDNA origin] Injection)

Important:

Know your insulin. Do not change the type of insulin you use unless told to do so by your health care provider. The amount of insulin you take as well as the best time for you to take your insulin may need to change if you take a different type of insulin.

Make sure you know the type and strength of insulin prescribed for you.

Read the Patient Information that comes with NovoLog before you start taking it and each time you get a refill. There may be new information. This leaflet does not take the place of talking with your health care provider about your diabetes or your treatment. Make sure you know how to manage your diabetes. Ask your healthcare provider if you have any questions about managing your diabetes.

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 use NovoLog?

Do not take NovoLog if:

- Your blood sugar is too low (hypoglycemia)
- You are allergic to anything in NovoLog. See the end of this leaflet for a complete list of ingredients in NovoLog. Check with your healthcare provider if you are not sure.

Tell your health care provider:

- **about all of your medical conditions.** Medical conditions can affect your insulin needs and your dose of NovoLog.
- **if you are pregnant or breastfeeding,** You and your healthcare provider should talk about the best way to manage your diabetes while you are pregnant or breastfeeding. NovoLog has not been studied in nursing women.
- **about all medicines you take,** including prescriptions and non-prescription medicines, vitamins and herbal supplements. Your NovoLog dose may change if you take other medicines.

Know the medicines you take. Keep a list of your medicines with you to show your healthcare providers when you get a new medicine.

How should I take NovoLog?

Only use NovoLog if it appears clear and colorless. There may be air bubbles. This is normal. If it looks cloudy, thickened, or colored, or if it contains solid particles do not use it and call Novo Nordisk at 1-800-727-6500.

NovoLog comes in:

- 10 mL vials (small bottles) for use with syringe
- 3 mL PenFill[®] cartridges for use with the Novo Nordisk 3 mL PenFill cartridge compatible insulin delivery devices and NovoFine[®] disposable needles. The cartridge delivery device can be used with a NovoPen[®] 3 PenMate[®]
- 3 mL NovoLog FlexPen[®]

Read the instructions for use that come with your NovoLog product. Talk to your healthcare provider if you have any questions. Your healthcare provider should show you how to inject NovoLog before you start taking it.

- **Take NovoLog exactly as prescribed.** You should eat a meal within 5 to 10 minutes after using NovoLog to avoid low blood sugar.
- **NovoLog is a fast-acting insulin.** The effects of NovoLog start working 10 to 20 minutes after injection or bolus pump infusion.
- **Do not inject NovoLog if you do not plan to eat right after your injection or bolus pump infusion.**
- The greatest blood sugar lowering effect is between 1 and 3 hours after the injection or infusion. This blood sugar lowering lasts for 3 to 5 hours.
- **While using NovoLog you may have to change** your total dose of insulin, your dose of longer-acting insulin, or the number of injections of longer-acting insulin you use. Pump users given NovoLog may need to change the amount of total insulin given as a basal infusion.
- **Do not mix NovoLog:**
 - with any other insulins when used in a pump
 - with any insulins other than NPH when used with injections by syringe

If your doctor recommends diluting NovoLog, follow your doctor's instructions exactly so that you know:

- How to make NovoLog more dilute (that is, a smaller number of units of NovoLog for a given amount of liquid) and
- How to use this more dilute form of NovoLog. **Do not use dilute insulin in a pump.**

- **Inject NovoLog into the skin of your stomach area, upper arms, buttocks or upper legs.** NovoLog may affect your blood sugar levels sooner if you inject it into the skin of your stomach area. **Never inject NovoLog into a vein or into a muscle.**
- **Change (rotate) your injection site within the chosen area (for example, stomach or upper arm) with each dose. Do not inject into the exact same spot for each injection.**
- **If you take too much NovoLog, your blood sugar may fall low (hypoglycemia).** You can treat mild low blood sugar (hypoglycemia) by drinking or eating something sugary right away (fruit juice, sugar candies, or glucose tablets). It is important to treat low blood sugar (hypoglycemia) right away because it could get worse and you could pass out (become unconscious). If you pass out you will need help from another person or emergency medical services right away, and will need treatment with a glucagon injection or treatment at a hospital. See “What are the possible side effects of NovoLog?” for more information on low blood sugar (hypoglycemia).
- **If you forget to take your dose of NovoLog, your blood sugar may go too high (hyperglycemia).** If high blood sugar (hyperglycemia) is not treated it can lead to serious problems, like loss of consciousness (passing out), coma or even death. Follow your healthcare provider’s instructions for treating high blood sugar. Know your symptoms of high blood sugar which may include:
 - increased thirst
 - frequent urination
 - drowsiness
 - loss of appetite
 - a hard time breathing
 - fruity smell on the breath
 - high amounts of sugar and ketones in your urine
 - nausea, vomiting (throwing up) or stomach pain
- **Check your blood sugar levels.** Ask your healthcare provider what your blood sugars should be and when you should check your blood sugar levels.

Your insulin dosage may need to change because of:

- illness
- stress
- other medicines you take
- change in diet
- change in physical activity or exercise

What should I avoid while using NovoLog?

- **Alcohol.** Alcohol, including beer and wine, may affect your blood sugar when you take NovoLog®.

- **Driving and operating machinery.** You may have difficulty concentrating or reacting if you have low blood sugar (hypoglycemia). Be careful when you drive a car or operate machinery. Ask your healthcare provider if it is alright to drive if you often have:
 - low blood sugar
 - decreased or no warning signs of low blood sugar

What are the possible side effects of NovoLog?

- **low blood sugar (hypoglycemia).** Symptoms of low blood sugar may include:
 - sweating
 - dizziness or lightheadedness
 - shakiness
 - hunger
 - fast heart beat
 - tingling of lips and tongue
 - trouble concentrating or confusion
 - blurred vision
 - slurred speech
 - anxiety, irritability or mood changes
 - headache

Severe low blood sugar can cause unconsciousness (passing out), seizures, and death. Know your symptoms of low blood sugar. Follow your healthcare provider's instructions for treating low blood sugar. Talk to your healthcare provider if low blood sugar is a problem for you.

- **Serious allergic reaction (whole body reaction).** Get medical help right away, if you develop a rash over your whole body, have trouble breathing, a fast heartbeat, or sweating.
- **Reactions at the injection site (local allergic reaction).** You may get redness, swelling, and itching at the injection site. If you keep having skin reactions or they are serious talk to your healthcare provider. You may need to stop using NovoLog and use a different insulin. Do not inject insulin into skin that is red, swollen, or itchy.
- **Skin thickens or pits at the injection site (lipodystrophy).** Change (rotate) where you inject your insulin to help to prevent these skin changes from happening. Do not inject insulin into this type of skin.
- **Swelling of your hands and feet.**
- **Vision changes**
- **Low potassium in your blood (hypokalemia)**

- **Weight gain**

These are not all of the possible side effects from NovoLog. Ask your healthcare provider or pharmacist for more information.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store NovoLog?

All Unopened NovoLog:

- **Keep all unopened NovoLog in the refrigerator between 36° to 46°F (2° to 8°C).**
- Do not freeze. Do not use NovoLog if it has been frozen.
- Keep unopened NovoLog in the carton to protect from light.

NovoLog in use:

- **Vials.**
 - Keep in the refrigerator or at room temperature below 86°F (30°C) for up to 28 days.
 - Keep vials away from direct heat or light.
 - Throw away an opened vial after 28 days of use, even if there is insulin left in the vial.
 - Do not draw up NovoLog into a syringe and store for later use
 - Unopened vials can be used until the expiration date on the NovoLog label, if the medicine has been stored in a refrigerator.
- **PenFill Cartridges or NovoLog FlexPen Prefilled syringe.**
 - Keep at room temperature below 86°F (30°C) for up to 28 days.
 - Do not store a PenFill cartridge or NovoLog FlexPen Prefilled syringe that you are using in the refrigerator.
 - Keep PenFill cartridges and NovoLog FlexPen Prefilled syringe away from direct heat or light.
 - Throw away a used PenFill cartridge or NovoLog FlexPen Prefilled syringes after 28 days, even if there is insulin left in the cartridge or syringe.
- **NovoLog in the pump reservoir and the complete external pump infusion set**

- The reservoir, tubing, and catheter-needle should be changed **at least every 48 hours**. Change more often than every 48 hours if you have high blood sugar (hyperglycemia), the pump alarm sounds, or the insulin flow is blocked (occlusion).

General advice about NovoLog

Medicines are sometimes prescribed for conditions that are not mentioned in the patient leaflet. 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 you have. It may harm them.

This leaflet summarizes the most important information about NovoLog. If you would like more information about NovoLog or diabetes, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about NovoLog that is written for healthcare professionals. Call 1-800-727-6500 or visit www.novonordisk-us.com for more information.

Helpful information for people with diabetes is published by the American Diabetes Association, 1660 Duke Street, Alexandria, VA 22314 and on www.diabetes.org.

NovoLog® ingredients include:

- insulin aspart
- glycerin
- phenol
- metacresol
- zinc
- disodium hydrogen phosphate dihydrate
- sodium chloride

All NovoLog vials, PenFill cartridges and NovoLog FlexPen Prefilled syringes are latex free.

Date of Issue: March 14, 2008

Version: 6

NovoLog®, PenFill®, FlexPen®, NovoPen®, NovoFine®, PenMate®, are trademarks of Novo Nordisk A/S.

NovoLog® is covered by US Patent Nos. 5,618,913, 5,866,538, and other patents pending.

FlexPen® is covered by US Patent Nos. 6,582,404, 6,004,297, 6,235,004, and other patents pending.

PenFill® is covered by US Patent Nos. 6,126,646, 5,693,027, DES 347894, and other patents pending.

© 2002-2008 Novo Nordisk Inc.

Manufactured by:
Novo Nordisk A/S
DK-2880 Bagsvaerd, Denmark

For information about NovoLog[®] contact:
Novo Nordisk Inc.
100 College Road West,
Princeton, New Jersey 08540