

Patient Information

NovoLog[®] (NŌ-vō-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 healthcare 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 healthcare 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 healthcare 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 healthcare provider recommends diluting NovoLog[®], follow your healthcare provider'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
 - loss of appetite
 - high amounts of sugar and ketones in your urine
 - nausea, vomiting (throwing up) or stomach pain
 - fruity smell on the breath
 - drowsiness
 - a hard time breathing
- **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
- change in physical activity or exercise
- change in diet
- other medicines you take

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
 - blurred vision
 - trouble concentrating or confusion
 - dizziness or lightheadedness
 - hunger
 - shakiness
 - slurred speech
 - fast heart beat
 - tingling of lips and tongue
 - 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 healthcare provider 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[®]**
 - Keep at room temperature below 86°F (30°C) for up to 28 days.
 - Do not store a PenFill[®] cartridge or NovoLog[®] FlexPen[®] that you are using in the refrigerator.
 - Keep PenFill[®] cartridges and NovoLog[®] FlexPen[®] away from direct heat or light.
 - Throw away a used PenFill[®] cartridge or NovoLog[®] FlexPen[®] 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 infusion set and the infusion site should be changed **at least every 3 days.** The insulin in the reservoir should be changed **at least every 6 days** even if you have not used all of the insulin. Change the infusion set and the infusion site more often than every 3 days 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, 1701 N Beauregard Street, Alexandria, VA 22311 and on www.diabetes.org.

NovoLog[®] ingredients include:

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

All NovoLog[®] vials, PenFill[®] cartridges and NovoLog[®] FlexPen[®] are latex free.

NovoLog[®], PenFill[®], FlexPen[®], NovoPen[®], NovoFine[®], and 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.

Manufactured by:
Novo Nordisk A/S
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Patient Instructions for Use

NovoLog® FlexPen®

Introduction

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

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

△ NovoLog® FlexPen® should not be used by people who are blind or have severe visual problems without the help of a person who has good eyesight and who is trained to use the NovoLog® FlexPen® the right way.

Getting ready

Make sure you have the following items:

- NovoLog® FlexPen®
- New NovoFine® needle
- Alcohol swab

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).

Wipe the rubber stopper with an alcohol swab.

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).

Never place a disposable needle on your NovoLog® FlexPen® until you are ready to take your injection.

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).

△ Always use a new needle for each injection to help ensure sterility and prevent blocked needles.

△ Be careful not to bend or damage the needle before use.

△ To reduce the risk of unexpected needle sticks, never put the inner needle cap back on the needle.

Giving the airshot before each injection

Before each injection small amounts of air may collect in the cartridge during normal use. To avoid injecting air and to ensure proper dosing:

E. Turn the dose selector to select 2 units (see diagram E).

F. Hold your NovoLog® FlexPen® with the needle pointing up. Tap the cartridge gently with your finger a few times to make any air bubbles collect at the top of the cartridge (see diagram F).

G. Keep the needle pointing upwards, press the push-button all the way in (see diagram G). The dose selector returns to 0.

A drop of insulin should appear at the needle tip. If not, change the needle and repeat the procedure no more than 6 times.

If you do not see a drop of insulin after 6 times, do not use the NovoLog® FlexPen® and contact Novo Nordisk at 1-800-727-6500.

A small air bubble may remain at the needle tip, but it will not be injected.

Selecting your dose

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

H. Turn the dose selector to the number of units you need to inject. The pointer should line up with your dose.

The dose can be corrected either up or down by turning the dose selector in either direction until the correct dose lines up with the pointer (see diagram H). When turning the dose selector, be careful not to press the push-button as insulin will come out.

You cannot select a dose larger than the number of units left in the cartridge.

You will hear a click for every single unit dialed. Do not set the dose by counting the number of clicks you hear.

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

Giving the injection

Do the injection exactly as shown to you by your healthcare provider. Your healthcare provider should tell you if you need to pinch the skin before injecting.

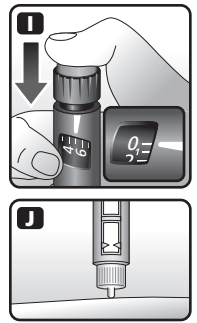
I. Insert the needle into your skin.

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 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.**



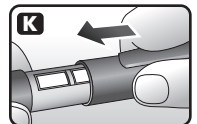
After the injection

Do not recap the needle. Recapping can lead to a needle stick injury. Remove the needle from the NovoLog® FlexPen® after each injection. This helps to prevent infection, leakage of insulin, and will help to make sure you inject the right dose of insulin.

△ Put the needle and any empty NovoLog® FlexPen® or any used NovoLog® FlexPen® still containing insulin in a sharps container or some type of hard plastic or metal container with a screw top such as a detergent bottle or empty coffee can. These containers should be sealed and thrown away the right way. Check with your healthcare provider about the right way to throw away used syringes and needles. There may be local or state laws about how to throw away used needles and syringes. Do not throw away used needles and syringes in household trash or recycling bins.

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).

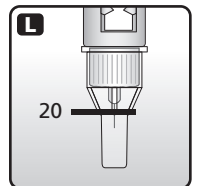


Function Check

L. If your NovoLog® FlexPen® is not working the right way, follow the steps below:

- Screw on a new NovoFine® needle.
- Remove the big outer needle cap and the inner needle cap.
- Do an airshot as described in "Giving the airshot before each injection".
- Put the big outer needle cap onto the needle. Do not put on the inner needle cap.
- Turn the dose selector so the dose indicator window shows 20 units.
- Hold the NovoLog® FlexPen® so the needle is pointing down.
- Press the push-button all the way in.

The insulin should fill the lower part of the big outer needle cap (see diagram L). If the NovoLog® FlexPen® has released too much or too little insulin, do the function check again. If the same problem happens again, do not use your NovoLog® FlexPen® and contact Novo Nordisk at 1-800-727-6500.



Maintenance

Your FlexPen® is designed to work accurately and safely. It must be handled 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.

△ Needles and NovoLog® FlexPen® must not be shared. 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.

