NovoLog® FlexPen®

Please see reverse side for easy to use instructions.

NovoLog FlexPen uses NovoFine® disposable needles,* designed to help improve injection comfort.

Each pen is prefilled with 300 units of insulin. Simply throw it away and start another when you’re done.

NovoLog FlexPen has a large, clear scale to help with accurate dose setting and adjustment.

Easy dose correction—simply dial backward or forward to change dose.

Please refer to the patient product information to see the detailed images of the pen.

Please see attached Prescribing Information. Pen shown at actual size.

*NovoFine disposable needles are sold separately and may require a prescription in some states.

NovoLog® FlexPen®
Insulin aspart (rDNA origin) injection
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Insulin aspart (rDNA origin) injection

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**What should I know about NovoLog® use?**

- Inject NovoLog® immediately after meal.
- The effects of NovoLog will start within 10 to 20 minutes after the injection is made.
- The maximum effect will be between 1 and 3 hours after the injection is made.
- The effect will last for 3 to 5 hours after the injection.

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**What to do if you miss an injection?**

- Do not double the dose to make up for the missed injection.
- If you miss your insulin dose, inject as soon as you remember. Do not wait until your next scheduled dose.

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

1. **NovoLog® is different than human regular insulin because it starts to work faster (rapid onset of action) and will not work as long (shorter duration of action) as human regular insulin. You should eat a meal within 5 to 10 minutes after your injection of NovoLog® to reduce the risk of low blood sugar (hypoglycemia). The shorter duration of action of NovoLog® means that if you have Type 1 diabetes, you may need to eat a meal within 5 to 10 minutes after your injection of NovoLog® or the long-acting insulin, or both. Patients taking NovoLog® may require a change in dose from that used with other insulins. If an adjustment is needed, it may occur with the first dose or during the first several weeks or months.**

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**What is diabetes, and how is insulin used to treat diabetes?**

- Insulin is normally produced by the pancreas, a gland that lies behind the stomach. Without insulin, glucose is trapped in the bloodstream and cannot enter the cells of the body. Glucose is a simple sugar made from the food you eat. Some people who do not make, or are not enough, of their own insulin, or who cannot use the insulin they do make, must take insulin by injection to control the amount of glucose in their (blood glucose level). If you depend on injections of insulin, injections of insulin combined with oral (taken by mouth) insulin, antibiotic, or an oral antidiabetic medicine alone.

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

- If you think you are having a generalized allergic reaction, notify a health care provider right away. If you notice any of these conditions, consult your health care provider. A change in your injection technique, for example, may reduce the problem.
- Always check your health care provider if you have any questions about your condition or the use of insulin.

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**How should I store NovoLog®?**

- Store insulin in a refrigerator, but not in the freezer. Do not use NovoLog® FlexPen Prefilled Syringes if it has been frozen. Keep unused NovoLog® FlexPen Prefilled syringes in the carton so that they will stay cool and protected from light.
- Do not use NovoLog® if it appears cloudy, thickened, slightly colored, or if solid particles are visible. Use it only if it is clear and colorless.
- Never use NovoLog® after the expiration date printed on the label and carton.

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**General advice about prescription medications**

Do not share your medicine with other people. It may harm them. If you have any questions about NovoLog®, talk with your health care provider. Your pharmacist or health care provider can give you the written information about NovoLog® that is attached to the drug package. You may also want to review the information provided by your pharmacist or health care provider. You may want to keep a written list of the medications you are taking to share with your health care provider at the time of your visits. The list may help prevent you from taking duplicate medications.

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**How should I give a NovoLog® FlexPen® Prefilled syringe injection?**

1. Be sure you have the correct needle for your NovoLog® FlexPen Prefilled syringe for injection.
2. The following areas are suitable for subcutaneous (under the skin) insulin injection: abdomen, thigh, and buttocks. You may choose any area to inject. You can use the same area each time you inject. If you use the same area, rotation is important and will help avoid the development of lipodystrophy. The long-acting insulins (e.g., NPH) have a longer duration of action. The shorter duration of action of NovoLog® means that if you have Type 1 diabetes, you may need to eat a meal within 5 to 10 minutes after your injection of NovoLog® or the long-acting insulin, or both. Patients taking NovoLog® may require a change in dose from that used with other insulins. If an adjustment is needed, it may occur with the first dose or during the first several weeks or months.

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**What should I know about insulin absorption?**

- A change in your injection technique or type of insulin could require a dosage adjustment. Any change in insulin should be made cautiously and only under medical supervision.
- Always check your health care provider if you have any questions about your condition or the use of your insulin. Do not take NovoLog® at any time except as directed by your health care provider.
NovoLog® FlexPen® Prefilled syringe directions for use

NovoLog FlexPen Prefilled syringe is a disposable dial-a-dose insulin delivery system able to deliver from 1 to a maximum of 60 units. The dose can be adjusted in 1 unit increments. NovoLog FlexPen Prefilled syringe is designed for use with NovoFine® single use needles or other products specifically recommended by Novo Nordisk. NovoLog FlexPen Prefilled syringe is not recommended for the blind or severely visually impaired without the assistance of a sighted individual trained in the proper use of the product.

Please read these instructions completely before using this device.

1. PREPARING THE SYRINGE

Pull off the cap. Wipe the rubber stopper with an alcohol swab.

A. Remove the protective tab from the disposable needle and screw the needle onto the FlexPen. Never place a disposable needle on your FlexPen until you are ready to give an injection. Remove the needle right after use. If the needle is not removed, some liquid may leak from the FlexPen.

B. Pull off the outer and inner needle caps.

Giving the airshot before each injection:

Small amounts of air may collect in the needle and insulin reservoir during normal use. To avoid injecting air and to ensure proper dosing, hold the syringe with the needle pointing up and tap the syringe gently with your finger so any air bubbles collect in the top of the reservoir. Remove both the plastic outer cap and the needle cap.

C. Dial 2 units.

D. Holding the syringe with the needle pointing up, tap the reservoir gently with your finger a few times. Still with the needle pointing up, press the push button as far as it will go and see if a drop of insulin appears at the needle tip. If not, repeat the procedure until insulin appears. Before the first use of each NovoLog FlexPen you may need to perform up to 6 airshots to get a droplet of insulin at the needle tip. If you need to make more than 6 airshots, do not use the syringe, and contact Novo Nordisk. A small air bubble may remain but it will not be injected because the operating mechanism prevents the reservoir from being completely emptied.

2. SETTING THE DOSE

The numbers on the insulin reservoir can be used to estimate the amount of insulin left in the syringe. Do not use these numbers to measure the insulin dose.

You cannot set a dose greater than the number of units remaining in the reservoir.

The dose can be adjusted in 1 unit increments. NovoLog FlexPen Prefilled syringe is designed for use with NovoFine® single use needles or other products specifically recommended by Novo Nordisk.

3. GIVING THE INJECTION

Use the injection technique recommended by your doctor.

Deliver the dose by pressing the push button all the way in. Be careful only to push the push button when injecting. After the injection the needle should remain under the skin for at least 6 seconds. Keep the push button fully depressed until the needle is withdrawn from the skin. This will ensure that the full dose has been delivered.

To avoid needlesticks, do not recap the needle. Throw away the needle safely after each injection.

It is important that you use a new needle for each injection. Health care professionals, relatives and other care givers should follow general precautionary measures for removal and disposal of needles to eliminate the risk of unintended needle penetration.

For more information see How do I give the injection on the reverse side of this insert.

4. SUBSEQUENT INJECTIONS

It is important that you use a new needle for each injection. Follow the directions in steps 1 – 3.

The numbers on the insulin reservoir can be used to estimate the amount of insulin left in the syringe. Do not use these numbers to measure the insulin dose.

You cannot set a dose greater than the number of units remaining in the reservoir.

5. FUNCTION CHECK

If your NovoLog FlexPen is not working properly, follow this procedure:

- Screw on a new NovoFine needle
- Give an airshot as described in sections C to D
- Put the outer needle cap onto the needle
- Dispense 20 units into the outer needle cap, holding the pen with the needle pointing downwards.
- The insulin should fill the lower part of the cap (as shown in figure H). If NovoLog FlexPen has released too much or too little insulin, repeat the test. If it happens again, contact Novo Nordisk and do not use your NovoLog FlexPen.

Dispose of the used NovoLog FlexPen carefully without the needle attached.

6. IMPORTANT NOTES

- If you need to perform more than 6 airshots before the first use of NovoLog FlexPen syringe to get a droplet of insulin at the needle tip, do not use the FlexPen.
- Never place a disposable needle on this syringe until you are ready to use it. Remove the needle immediately after use.
- Throw away used needles in a responsible manner, so others will not be harmed.
- Throw away the used syringe, without the needle attached.
- Always carry a spare NovoLog FlexPen syringe with you in case your FlexPen is damaged or lost.
- Novo Nordisk cannot be held responsible for adverse reactions occurring as a consequence of using this insulin delivery system with products that are not recommended by Novo Nordisk.
- Keep this syringe out of the reach of children.

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NovoLog® is covered by U.S. Patent Nos. 5,618,913; 5,866,538 and other patents pending.
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NovoLog® FlexPen® 4 Simple Steps for Use

Please refer to the attached patient product information for full instructions for use.

**Step 1. Getting started:** Wash your hands. Pull off the pen cap and wipe the rubber stopper with an alcohol swab. Remove the protective tab from a NovoFine® single-use needle and screw it onto the prefilled NovoLog FlexPen. Place a new NovoFine needle on NovoLog FlexPen for each injection. Pull off the outer and inner needle caps.

**Step 2. Performing the airshot before injection:** Turn the dial to 2 units. Holding NovoLog FlexPen with the needle pointing up, tap the reservoir gently with your finger a few times. With the needle still pointing up, press the push button as far as it will go and see if a drop of insulin appears at the needle tip. If not, repeat this procedure (called an airshot) until a drop of insulin appears. **If no drop appears after 6 airshots, do not use NovoLog FlexPen and contact Novo Nordisk at 1-800-727-6500.**

**Step 3. Setting the dose:** Check that the dose selector is set at zero. Dial the number of units you need to inject. Do not set the dose by counting the number of clicks you hear. The dose can be corrected either up or down by turning the dose dial in either direction. When dialing back, be careful not to press the push button, as insulin will come out. You cannot set a dose for more than the number of units remaining in the reservoir.

**Step 4. Giving the injection:** Choose the injection site. Use the injection technique recommended by your doctor or healthcare professional. Push the NovoFine needle into the skin. Press the push button all the way in.

With the push button fully depressed, keep the NovoFine needle in the skin for at least 6 seconds to ensure the full dose has been delivered. Keep the push button fully depressed until the NovoFine needle is withdrawn from the skin.

To avoid needle sticks, **do not** recap the NovoFine needle. Remove the needle right after injection, before replacing the pen cap. Place the NovoFine needle in a “sharps” container (such as a red biohazard container) or in a hard plastic or metal container such as a detergent bottle or an empty coffee can. Seal and dispose of the container properly. Place the cap on NovoLog FlexPen for storage.

**Later injections:** Follow steps 1 to 4. It is important that you use a new NovoFine needle for each injection. The numbers on the insulin reservoir estimate the amount of insulin left in NovoLog FlexPen. Do not use these numbers to measure the insulin dose.

**After initial use, NovoLog FlexPen may be used for up to 28 days if it is kept at room temperature, below 86°F. In-use FlexPen must NOT be stored in a refrigerator and must NOT be stored with the needle in place.**

If your NovoLog FlexPen is not working properly, perform a function check according to the attached patient product information.

If you have questions about NovoLog FlexPen, call Novo Nordisk at 1-800-727-6500. Any change in insulin should be made cautiously and only under medical supervision.