



## insulin detemir (rDNA origin) injection

### Patient Information

#### Levemir® (LEV-uh-mere)

(insulin detemir [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 Levemir® 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 that you know how to manage your diabetes. Ask your healthcare provider if you have any questions about managing your diabetes.

#### What is Levemir®?

Levemir® is a man-made long-acting insulin that is used to control high blood sugar in adults and children with diabetes mellitus.

#### Who should not use Levemir®?

##### Do not take Levemir® if:

- Your blood sugar is too low (hypoglycemia).
- You are allergic to anything in Levemir®. See the end of this leaflet for a complete list of ingredients in Levemir®. 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 Levemir®.
- **if you are pregnant or breast-feeding.** You and your healthcare provider should talk about the best way to manage your diabetes while you are pregnant or breastfeeding. Levemir® has not been studied in pregnant or nursing women.
- **about all medicines you take,** including prescriptions and non-prescription medicines, vitamins and herbal supplements. Your Levemir® 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 provider when you get a new medicine.

#### How should I take Levemir®?

Only use Levemir® 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.

Levemir® comes in:

- 10 mL vials (small bottles) for use with a 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 Levemir® FlexPen®
- 3 mL Levemir® InnoLet®

#### Read the instructions for use that come with your Levemir® product.

Talk to your healthcare provider if you have any questions. Your healthcare provider should show you how to inject Levemir® before you start taking it.

- **Take Levemir® exactly as prescribed.**

- **Levemir® is a long-acting insulin.** The effect of Levemir® may last up to 24 hours after injection.

- **Inject Levemir® into the skin of your stomach area, upper arms, or thighs.** Levemir® may affect your blood sugar levels sooner if you inject it into the skin of your stomach area or

upper arm. **Never inject Levemir® 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 Levemir®, 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 Levemir®?" for more information on low blood sugar (hypoglycemia).
- **If you forget to take your dose of Levemir®, 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.
- **Never mix Levemir® with other insulin products.**
- **Never use Levemir® in an insulin pump.**

#### 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 Levemir®?

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

- **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 Levemir® 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)**

These are not all of the possible side effects from Levemir®. 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 Levemir®?

##### All Unopened Levemir®:

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

##### Levemir® in use:

- **Vials**
  - Keep in the refrigerator or at room temperature below 86°F (30°C) for up to 42 days.
  - Keep vials away from direct heat or light.
  - Throw away an opened vial after 42 days of use, even if there is insulin left in the vial.
  - Unopened vials can be used until the expiration date on the Levemir® label, if the medicine has been stored in a refrigerator.
- **Levemir® FlexPen®**
  - Keep at room temperature below 86°F (30°C) for up to 42 days.
  - Do not store a Levemir® FlexPen® that you are using in the refrigerator.
  - Keep Levemir® FlexPen® away from direct heat or light.
  - Throw away a used Levemir® FlexPen® after 42 days, even if there is insulin left in the syringe.

#### General advice about Levemir®

Medicines are sometimes prescribed for conditions that are not mentioned in the patient leaflet. Do not use Levemir® for a condition for which it was not prescribed. Do not give Levemir® to other people, even if they have the same symptoms you have. It may harm them.

This leaflet summarizes the most important information about Levemir®. If you would like more information about Levemir® or diabetes, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about Levemir® that is written for healthcare professionals. Call 1-800-727-6500 or visit [www.novonordisk-us.com](http://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](http://www.diabetes.org).

#### Levemir® ingredients include:

- Insulin detemir
- Glycerol
- Phenol
- Metacresol
- Zinc
- Disodium hydrogen phosphate dihydrate
- Sodium chloride
- Water for injection
- Hydrochloric acid or sodium hydroxide

All Levemir® vials and Levemir® FlexPen® are latex free.

**Patient Instructions for Use**  
**Levemir® FlexPen®**

**Introduction**

Please read the following instructions carefully before using your Levemir® FlexPen®. Levemir® FlexPen® is a disposable dial-a-dose insulin pen. You can select doses from 1 to 60 units in increments of 1 unit. Levemir® FlexPen® is designed to be used with NovoFine® needles.

△ Levemir® 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 Levemir® FlexPen® the right way.

**Getting ready**

Make sure you have the following items:

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

**Preparing your Levemir® 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. Levemir® 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 Levemir® 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 Levemir® 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 Levemir® 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.

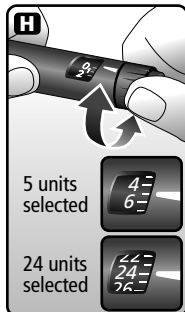
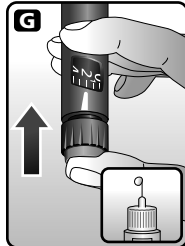
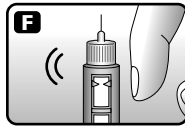
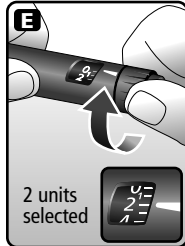
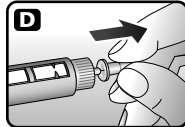
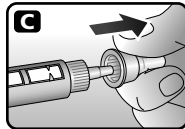
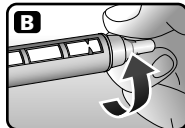
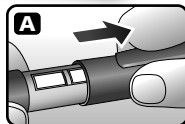
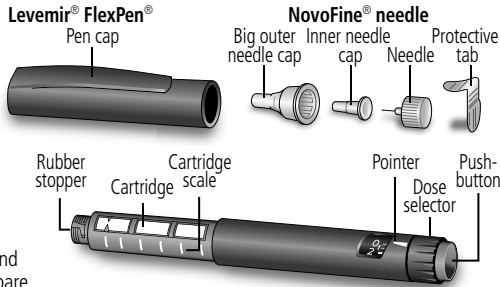
You will hear a click for every single unit dialed. Do not set the dose by counting the number of clicks you hear.

- △ 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.

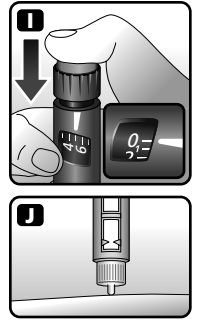


Inject the dose by pressing the push-button all the way in until the 0 lines up with the pointer (see diagram I). Be careful only to push the button when injecting.

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 Levemir® 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 Levemir® 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.

The Levemir® FlexPen® prevents the cartridge from being completely emptied. It is designed to deliver 300 units.

- △ Put the needle and any empty Levemir® FlexPen® or any used Levemir® 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.

- K.** Put the pen cap on the Levemir® FlexPen® and store the Levemir® FlexPen® without the needle attached (see diagram K).

**Function Check**

If your Levemir® FlexPen® is not working the right way, follow the steps below:

- L.**
- 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 Levemir® 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 Levemir® FlexPen® has released too much or too little insulin, do the function check again. If the same problem happens again, do not use your Levemir® 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 Levemir® 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 Levemir® FlexPen® and needles out of the reach of children.  
△ Use Levemir® FlexPen® as directed to treat your diabetes. Needles and Levemir® 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 Levemir® FlexPen® is lost or damaged.  
△ Remember to keep the disposable Levemir® FlexPen® with you. Do not leave it in a car or other location where it can get too hot or too cold.

Levemir®, PenFill®, FlexPen®, InnoLet®, NovoLet®, NovoFine®, and PenMate® are trademarks of Novo Nordisk A/S. Levemir® is covered by US Patent Nos. 5,750,497; 5,866,538; 6,011,007; 6,869,930, 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.

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