



## Patient Information Sheet

### Insulin detemir [rDNA origin] injection (marketed as Levemir)

This is a summary of the most important information about Levemir. For details, talk to your healthcare professional.

#### What Is Levemir?

- Levemir (insulin detemir [recombinant DNA origin]) is a long-acting insulin used to treat adult patients with diabetes for the control of high blood sugar.
- Because Levemir is made by recombinant DNA technology (rDNA) and is chemically different from the insulin made by the human body, it is called an insulin analog.

#### Who Should Not Use Levemir?

Do not take Levemir if:

- your blood sugar is too low (hypoglycemia)
- you are allergic to insulin detemir or any of its ingredients.

#### What Are The Risks?

**Hypoglycemia (low blood sugar)** can occur with:

- the wrong insulin dose.
- medicines that directly lower glucose or increase sensitivity to insulin.
- medical conditions that limit the body's glucose reserve, lengthen the time insulin stays in the body, or that increase sensitivity to insulin.
- not enough carbohydrate (sugar or starch) intake.
- too much glucose use by the body.

**Hyperglycemia (high blood sugar)** can occur with:

- the wrong insulin dose.
- medicines that directly increase glucose or decrease sensitivity to insulin.
- medical conditions that increase the body's production of glucose or decrease sensitivity to insulin.
- too much carbohydrate intake.

Talk to your healthcare professional about symptoms of hypoglycemia or hyperglycemia.

Other possible side effects include the following:

- **Serious allergic reaction.** Get medical help right away if you develop a rash over your whole body, have trouble breathing, a fast heartbeat, or sweating.
- **Reaction at the injection site** (local allergic reaction). You may get redness, swelling and itching at the injection site. If you have serious or continuing reactions, you may need to stop using Levemir and use another insulin.
- **Skin thickens or pits at the injection site**, especially if the injection site is not rotated.

- **Vision changes** that may require evaluation by an ophthalmologist (medical doctor specializing in eye disease) or changes in your eyeglasses or contact lens prescription.
- **Fluid retention or swelling of your hands and feet.**
- **Low potassium in your blood** (hypokalemia).

#### What Should I Tell My Healthcare Professional?

Before starting Levemir, tell your healthcare professional about all your medical conditions including if you:

- **have liver or kidney problems.**
- **are pregnant or planning to become pregnant or are breast-feeding or planning to breast-feed.**
- **take any other medicines.**

#### Are There Any Interactions With Drugs Or Foods?

Tell your healthcare professional about all the medicines you are taking including prescription and nonprescription medicines, vitamins, and herbal supplements. Certain medicines may increase or decrease glucose or may increase or decrease sensitivity to insulin. **Do not start any new medicines until you know how they may affect your insulin dose.**

- **Many medicines may affect your insulin needs.** Other medicines can change the way insulin works. You may need a different dose of insulin when you are taking certain other medicines. Keep a list to show to your health care professional. Do not start any new medicines until you know how they may affect your insulin dose.
- **The amount of food you eat can affect your insulin needs.** Talk to your doctor if you change your diet so that you know how to adjust your Levemir and other insulin doses.
- **Alcohol, including beer and wine, may affect your blood sugar levels.** Talk to your health care professional about drinking alcohol.

#### How Do I Take Levemir?

- Follow your healthcare professional's instruction about monitoring your blood sugar. Do not make any changes with your insulin unless you have talked to your doctor. Your insulin needs may change because of illness, stress, other medicines, or changes in diet or activity level. Talk to your doctor about how to adjust your insulin dose.
- Levemir can be taken once or twice daily. Your Levemir dose and frequency of dosing should be individualized based on your doctor's advice.
- Before injecting Levemir make sure that you have the correct type and strength of insulin.
- Carefully follow the instructions on how to use your insulin syringe or insulin Pen.
- Levemir should NOT be mixed with any other insulin or solution.
- Levemir is NOT to be used in insulin infusion pumps.





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**Levemir FDA Approved June 2005  
Patient Information Sheet Created 06/2005**



*Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570  
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