

CONSUMER INFORMATION
Product Monograph Part III

LEVEMIR[®]
insulin detemir
100 U/mL, solution for injection

Novo Nordisk Canada Inc.

Submission Control No. 081683

The Consumer Information Section (Part III) of the Product Monograph for LEVEMIR[®] has been submitted by the drug sponsor and is attached for your information.

The attached version accompanied the Notice of Compliance issued on September 29, 2005, and does not necessarily reflect the most current information for the product.

For the most up-to-date product information, please consult your health care professional.

Due to the fact that the information originated with an organization that is not subject to the *Official Languages Act*, the document may only appear in the language in which it was written. Translations of the document are the responsibility of the sponsor involved.

Levemir[®] Penfill[®]

insulin detemir
solution for injection 3 mL

Read all of this leaflet carefully before you start using your insulin. Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor, Diabetes Nurse Educator or your pharmacist.

This medicine is prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

Levemir[®] Penfill[®] 100 U/mL Solution for injection in a Penfill[®] cartridge containing insulin detemir produced by recombinant DNA methods followed by unique purification processes. **The active substance** in Levemir[®] is insulin detemir made by recombinant biotechnology. 1 mL contains 100 U (units) of insulin detemir. 1 Penfill[®] cartridge contains 3 mL of insulin detemir equivalent to 300 U. **Levemir[®] Penfill[®] also contains:** mannitol, phenol, metacresol, zinc acetate, disodium phosphate dihydrate, sodium chloride, hydrochloric acid, sodium hydroxide, and Sterile Water for Injection. The solution for injection is a clear, colourless, aqueous solution.

1 What is Levemir[®] Penfill[®] and what is it used for

Levemir[®] Penfill[®] is a human insulin analogue used to treat diabetes. Levemir[®] is a long-acting human insulin analogue which lowers your blood glucose. Levemir[®] has a flat and predictable profile for blood glucose control. The effect will last for up to 24 hours depending on the dose.

Levemir[®] is available from Novo Nordisk Canada in the following format: Levemir[®] Penfill[®] 3 mL cartridge (designed for use with Novo Nordisk Insulin Delivery Devices)

Levemir[®] Penfill[®] cartridges are designed for use with Novo Nordisk Insulin Delivery Systems and NovoFine[®] needles. Novo Nordisk cannot be held responsible for malfunctions occurring as a consequence of using Levemir[®] Penfill[®] cartridges in combination with products that do not meet the same specifications or quality standards.

2 Before you use Levemir[®] Penfill[®]

Do not use Levemir[®]

- ▶ **If you feel a hypo** coming on (a hypo is short for a hypoglycemic reaction and is a symptom of low blood sugar). See 4 *What to do in an emergency*, for more about hypos.
- ▶ **If you are allergic (hypersensitive)** to insulin detemir, metacresol or any of the other ingredients (see box, below left). Look out for the signs of an allergic reaction (see 5 *Possible side effects*).

Take special care with Levemir[®]

- ▶ **If you have trouble** with your kidneys or liver, or with your adrenal, pituitary or thyroid glands.
- ▶ **If you drink alcohol:** watch for signs of a hypo.
- ▶ **If you exercise more than usual** or if you want to change your usual diet.
- ▶ **If you are ill:** continue taking your insulin.
- ▶ **If you go abroad:** travelling over time zones may affect your insulin needs.
- ▶ **If you are pregnant, or planning a pregnancy or are breastfeeding** please contact your doctor for advice.
- ▶ **If you drive or use tools or machines:** watch for signs of a hypo. Your ability to concentrate or to react will be less during a hypo. Never drive or use machinery if you feel a hypo coming on. Discuss with your doctor whether you should drive or use machines at all, if you have a lot of hypos or if you find it hard to recognize hypos.

When to use other medicines

Many medicines affect the way glucose works in your body and this may influence your insulin dose. Listed below are the most common medicines, which may affect your insulin treatment. Talk to your doctor or pharmacist if you take, or change any other medicines, even those not prescribed. **Your need for insulin may change** if you also take: oral antidiabetic medicinal products; monoamine oxidase inhibitors; (MAOI); beta-blockers; ACE-inhibitors; acetylsalicylic acid (aspirin); thiazides; glucocorticoids; thyroid hormone therapy; beta-sympathomimetics; growth hormone; danazol; octreotide and lanreotide.

3 How to use Levemir[®] Penfill[®]

Talk about your insulin needs with your doctor and Diabetes Nurse Educator. Follow their advice carefully. This leaflet is a general guide. If your doctor has switched you from one type or brand of insulin to another, your dose may have to be adjusted by your doctor.

Before using Levemir[®]

- ▶ **Check the label to make sure** you have the right type of insulin.
- ▶ **Always check** the Penfill[®] cartridge, including the rubber stopper (plunger). Don't use it if any damage is seen or if the part of the rubber stopper that you can see exceeds the white barcode band. Take it back to your supplier or call Novo Nordisk Canada at 1 800 465-4334 for assistance.
- ▶ **Disinfect** the rubber membrane with an alcohol swab.

Do not use Levemir[®]

- ▶ **In insulin infusion pumps.**
- ▶ **If the Penfill[®] cartridge or Novo Nordisk Insulin Delivery Device containing the cartridge is dropped, damaged or crushed;** there is a risk of leakage of insulin.
- ▶ **If the insulin has not been stored correctly** or if it has been frozen (see 6 *How to store Levemir[®] Penfill[®]*).
- ▶ **If the insulin does not appear water-clear and colourless.**

Do not refill a Levemir[®] Penfill[®] cartridge. Levemir[®] Penfill[®] cartridges are designed to be used with Novo Nordisk Insulin Delivery Devices and NovoFine[®] needles as part of **The All-In-One Insulin System[®]**. If you are treated with Levemir[®] Penfill[®] and another insulin in Penfill[®] cartridge, you should use two Novo Nordisk Insulin Delivery Devices, one for each type of insulin.

How to use this insulin

Levemir[®] is for injection under the skin (subcutaneously). Never inject your insulin directly into a vein or muscle. **Always vary the sites you inject,** to avoid lumps (see 5 *Possible side effects*). The best places to give yourself an injection are: the front of your thighs; the front of your waist (abdomen); or the upper arm. You should always measure your blood glucose regularly.

How to inject this insulin

- ▶ **Inject the insulin under the skin.** Use the injection technique advised by your doctor or Diabetes Nurse Educator and described in your Novo Nordisk Insulin Delivery Device manual.
- ▶ **Keep the needle under your skin** for at least 6 seconds to make sure that the full dose has been delivered.
- ▶ **After each injection** be sure to remove the needle. Otherwise, insulin may leak out.

4 What to do in an emergency

If you get a hypo

A hypo means your blood sugar level is too low. **The warning signs of a hypo** may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heart beat; feeling sick; feeling very hungry; temporary changes in vision; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; and difficulty concentrating.

If you get any of these signs: eat glucose tablets or a high sugar snack (sweets, biscuits, fruit juice), then rest. **Don't take any insulin** if you feel a hypo coming on.

Carry glucose tablets, sweets, biscuits or fruit juice with you, just in case. **Tell people that if you pass out** (become unconscious), they should: turn you on your side and get medical help right away. They should not give you anything to eat or drink. It could choke you.

- ▶ **If severe hypoglycemia** is not treated, it can cause brain damage (temporary or permanent) and even death.
- ▶ **If you have a hypo** that makes you pass out, or if you get hypos often, talk to your doctor. The amount or timing of your insulin dose, the amount of food you eat or the amount of exercise you do, may need to be adjusted.

Using glucagon

You may recover more quickly from unconsciousness with an injection of the hormone glucagon given by someone who knows how to use it. If you are given glucagon you will need glucose or a sugary snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital. Contact your doctor or hospital emergency after an injection of glucagon: you need to find the reason for your hypo in order to avoid getting more.

Causes of a hypo

You get a hypo if your blood sugar gets too low. This might happen:

- If you take too much insulin.
- If you eat too little or miss a meal.
- If you exercise more than usual.

If your blood sugar gets too high

Your blood sugar may get too high (this is called hyperglycemia). **The warning signs** appear gradually. They include: increased urination; feeling thirsty; losing your appetite; feeling sick (nausea or vomiting); feeling drowsy or tired; flushed or dry skin; a dry mouth and a fruity (acetone) smelling breath. **If you get any of these signs:** test your blood sugar level; test your urine for ketones if you can; then seek medical advice right away.

These may be signs of a very serious condition called diabetic ketoacidosis. If you don't treat it, this could lead to diabetic coma and death.

Causes of hyperglycemia

- Forgetting to take your insulin.
- Repeatedly taking less insulin than you need.
- An infection or fever.
- Eating more than usual.
- Exercising less than usual.

5 Possible side effects

Like all medicines, Levemir[®] can have side effects. Taking too much Levemir[®] may cause low blood sugar (hypoglycemia). See the advice in 4 *What to do in an emergency*.

Commonly reported side effects

(less than 1 in 10)

Changes at the injection site. Reactions (redness, swelling, itching) at the injection site may occur. These usually disappear after a few weeks of taking your insulin. If they do not disappear see your doctor.

Less commonly reported side effects

(less than 1 in 100)

Signs of allergy. Hives and rash may occur.

Seek medical advice immediately:

- If the above signs of allergy appear or
- If you suddenly feel unwell, and you: start sweating; start being sick (vomiting); have difficulty breathing; have a rapid heart beat; feel dizzy.

You may have a very rare serious allergic reaction to Levemir[®] or one of its ingredients (called a generalized allergic reaction). See also the warning in 2 *Before you use Levemir[®] Penfill[®]*.

Vision problems. When you first start your insulin treatment, it may disturb your vision, but the disturbance is usually temporary.

Changes at the injection site. If you inject yourself too often in the same spot, lumps may develop underneath your skin. Prevent this by choosing a different injection site each time, within the same area.

Swollen joints. When you start taking insulin, water retention may cause swelling around your ankles and other joints. This soon disappears.

Rarely reported side effects

(less than 1 in 1,000)

Disturbing sensations. Fast improvement in blood glucose control may cause disturbing sensations (numbness, weakness or pain) in the legs or arms. These symptoms normally disappear. If you notice any side effects, including those not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting suspected side effects

To monitor drug safety, Health Canada collects information on serious and unexpected effects of drugs. If you suspect you have had a serious or unexpected reaction to Levemir[®] you may notify Health Canada by: Toll-free telephone: 866-234-2345 Toll-free fax: 866-678-6789 By email: cadmp@hc-sc.gc.ca By regular mail: National AR Centre Marketed Health Products Safety and Effectiveness, Information Division Marketed Health Products Directorate Tunney's Pasture, AL 0701C Ottawa, ON K1A 0K9 Before contacting Health Canada you should contact your physician or pharmacist.

6 How to store Levemir[®] Penfill[®]

Keep out of the reach and sight of children. **Levemir[®] Penfill[®] that is not being used** should be stored in the fridge between 2°C and 8°C away from the freezer compartment. Do not freeze. **Levemir[®] Penfill[®] that is being used** or is carried as a spare should not be kept in the fridge. You can carry it with you and keep it at room temperature (not above 30°C) for up to 42 days. Always keep your Levemir[®] Penfill[®] cartridge in its outer carton when you are not using it, in order to protect it from light. Levemir[®] Penfill[®] should be protected from excessive heat and sunlight. Do not use Levemir[®] Penfill[®] after the expiry date printed on the label and carton.

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DEVICES MATTER[®]

Insulin Pens




Novolin-Pen[®] 4 The reliable choice Novolin-Pen[®] Junior Better by half!

Insulin Doser



Innovo[®]
INSULIN DOSERS

NovoFine[®] Needles




32G 30G

The Canadian Diabetes Association Guidelines encourages the use of insulin delivery devices as they make multiple daily injections easier. Please call Medical Services at 1-800-465-4334 for more information.

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Reference: 1 Canadian Diabetes Association 2003 Clinical Practice Guidelines for the Prevention and Management of Diabetes in Canada. *Can. J Diabetes*. 2003;27(suppl. 2): S1-S152

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