

PART III: CONSUMER INFORMATION

Levemir[®] (insulin detemir)

This leaflet is part III of a three-part “Product Monograph” published when **Levemir[®]** was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about **Levemir[®]**.

Contact your doctor or pharmacist if you have any questions about this drug.

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 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.

ABOUT THIS MEDICATION

A direction leaflet containing information for the patient is included in each package.

What is *Levemir[®]*

Levemir[®] (insulin detemir) 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. It may be used in combination with oral antidiabetic agents or with meal-related short- or rapid-acting insulins. Compared to other insulins, therapy with **Levemir[®]** is associated with less weight gain.

Levemir[®] (insulin detemir) is indicated for:

- The treatment of adult patients with type 1 or type 2 diabetes mellitus who require a long-acting (basal) insulin for the control of hyperglycemia.
- The treatment of pediatric patients with type 1 diabetes mellitus who require a long-acting (basal) insulin for the control of hyperglycemia. The safety and efficacy of **Levemir[®]** has not been studied in children below the age of 6 years.
- the treatment of type 2 diabetes mellitus in combination with oral anti-diabetic agents (OADs) in adult patients who are not in adequate metabolic control on OADs alone.

Levemir[®] is also recommended in combination with short or rapid-acting meal-time insulin.

When *Levemir*[®] should not be used.

Do not use *Levemir*[®]:

- If you feel a hypo coming on (a hypo is short for a hypoglycemic reaction or low blood sugar). See *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 in this insulin. Look out for the signs of an allergic reaction (see *Possible side effects*).

What the medicinal ingredient is

The active ingredient in *Levemir*[®] is a human insulin analogue called *insulin detemir*.

What the nonmedicinal ingredients are:

Disodium phosphate dihydrate, glycerol, metacresol, phenol, sodium chloride, acetate and water for injection. Hydrochloric acid and/or sodium hydroxide may be added to adjust pH.

For a full listing of nonmedicinal ingredients see Part I of the product monograph.

Dosage forms

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 as NovoFine[®] needles.

WARNINGS AND PRECAUTIONS

Before you use *Levemir*[®] talk to your doctor or pharmacist:

- 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.

Before you travel, check with your physician or pharmacist on the availability of **Levemir**[®] in other countries. If possible, bring enough **Levemir**[®] with you on your trip.

INTERACTIONS WITH THIS MEDICATION

When you 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 products; monoamine oxidase inhibitors; (MAOI); beta-blockers; ACE-inhibitors; acetylsalicylic acid (aspirin); thiazides; glucocorticoids (except topical administration); thyroid hormone therapy; beta-sympathomimetics; growth hormone; danazol; octreotide and lanreotide.

PROPER USE OF THIS MEDICATION

How to use **Levemir**[®]

Talk about your insulin needs with your doctor and Diabetes Nurse Educator. Follow their advice carefully. This leaflet is a general guide only.

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 there is a gap between the rubber stopper and the white barcode label. Take it back to your supplier or call Novo Nordisk Canada at 1 800 465-4334 for assistance. See your Novo Nordisk Insulin Delivery Device manual for further instructions.
- 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 *How to Store Levemir*[®]).
- 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 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.

As a precautionary measure, you should carry a spare syringe and extra insulin in case the insulin delivery device is lost or damaged.

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 within the same region, to avoid lumps (see *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 when the temperature changes.

Overdose

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 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.

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

What to do in an emergency

If you get a hypo (hypoglycemia):

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 your relatives, friends and close colleagues that if you pass out (become unconscious), they must turn you on your side and get medical help right away.

They must not give you anything to eat or drink as 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 a lot of hypos, 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 to eat 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.

Possible side effects

Like all medicines, **Levemir**[®] can cause side effects, although not everybody gets them. Taking too much **Levemir**[®] may cause low blood sugar (hypoglycemia). Hypoglycemia is the most common side effect of insulin, including **Levemir**[®]. See the advice in *What to do in an emergency*.

Commonly reported side effects (less than 1 in 10):

Changes at the injection site. Reactions (redness, swelling, inflammation, itching and bruising) 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. If you have serious or continuing reactions, you may need to stop using **Levemir**[®] and use another insulin.

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 *Before you use Levemir*[®].

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 at the same site, fatty tissue under the skin at this injection site may shrink (lipoatrophy) or thicken (lipohypertrophy). Changing the site with each injection may help to prevent skin changes. If you notice your skin pitting or thickening at the injection site, tell your doctor or Diabetes Nurse Educator because these reactions can become more severe, or they may change the absorption of your insulin at this site.

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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, Diabetes Nurse Educator or your pharmacist.

HOW TO STORE IT

How to store *Levemir*[®]

Keep out of the reach and sight of children.

Levemir[®] that is not being used should be stored in the fridge between 2°C - 8°C, away from the freezer compartment. Do not freeze.

Levemir[®] that is being used or is carried as a spare should not to 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.

Penfill[®]: Always keep your Penfill[®] cartridge in the outer carton when you are not using it, in order to protect it from light.

Levemir[®] should be protected from excessive heat and sunlight.

Do not use **Levemir**[®] after the expiry date printed on the label and carton.

Levemir[®] should not be disposed of in waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

REPORTING SUSPECTED SIDE EFFECTS

To monitor drug safety, Health Canada through the Canada Vigilance Program collects information on serious and unexpected side effects of drugs. If you suspect you have had a serious or unexpected reaction to this drug you may notify Canada Vigilance:

By toll-free telephone: 1-866-234-2345

By toll-free fax: 1-866-678-6789

Online: www.healthcanada.gc.ca/medeffect

By email: CanadaVigilance@hc-sc.gc.ca

By regular mail:

Canada Vigilance National Office
Marketed Health Products Safety and Effectiveness
Information Bureau
Marketed Health Products Directorate
Health Products and Food Branch
Health Canada
Tunney's Pasture, AL 0701C
Ottawa ON K1A 0K9

Note: Should you require information related to the management of the side effect, please contact your healthcare provider before notifying Canada Vigilance. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

What **Levemir**[®] looks like and package content

Levemir[®] Penfill[®] comes as a clear, colourless, aqueous solution of 5 cartridges of 3 mL per carton.

1 mL contains 100 U (units) of insulin detemir.

1 Penfill[®] cartridge contains 3 mL equivalent to 300 U.

This document plus the full Product Monograph, prepared for health professionals can be obtained by contacting the sponsor, Novo Nordisk Canada, at 1-800-465-4334

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