Read this carefully before you start taking Levemir® and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Levemir®.

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.

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, Diabetes Nurse Educator or your pharmacist. If you have any trouble reading this, ask a family member or a friend for help.

### Serious Warnings and Precautions
- Hypoglycemia is the most common adverse effect of insulin, including Levemir®.
- If hypoglycemia or hyperglycemic reactions are not treated they can result in the loss of consciousness, coma or death.
- Glucose monitoring is recommended for all patients with diabetes.
- Any change of insulin should be made cautiously and only under medical supervision. This may result in dosage adjustment.
- Never inject your insulin directly into a vein.
- Never use Levemir® in insulin infusion pumps.
- Do not use Levemir® if it does not appear water clear or colourless.
- Levemir® must not be mixed with any other insulin.

### What is Levemir® (insulin detemir) used for?
- The treatment of type 1 diabetes mellitus in adults, adolescents and children aged 2 years and above.
- The treatment of type 2 diabetes mellitus in adults when insulin is required for the control of hyperglycemia.
- The treatment of type 2 diabetes mellitus in combination with oral antidiabetic agents (OADs) in adults who are not in adequate metabolic control on OADs alone.
- The treatment of type 2 diabetes mellitus in combination with liraglutide and metformin when liraglutide and metformin do not achieve adequate glycemic control.

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

### How does Levemir® work?
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, glucagon-like peptide (GLP)-1 receptor agonist or with meal-related short- or rapid-acting insulins. Compared to other insulins, therapy with Levemir® is associated with less weight gain.
What are the ingredients in Levemir®?
Medicinal ingredients: The active ingredient in Levemir® is a human insulin analogue called insulin detemir.
Non-medicinal ingredients: Disodium phosphate dihydrate, glycerol, metacresol, phenol, sodium chloride, zinc acetate and water for injection. Hydrochloric acid and/or sodium hydroxide may be added to adjust pH.

Levemir® comes in the following dosage forms:
Levemir® is available from Novo Nordisk Canada in the following formats:
• Levemir® Penfill® 3 mL cartridge (designed for use with Novo Nordisk Insulin Delivery Devices)
• Levemir® FlexTouch® 3 mL prefilled pen

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

Do not use Levemir® if:
• You feel a hypoglycemic reaction (low blood sugar) coming on. (see 'What are possible side effects from using Levemir®?' for more about hypoglycemia).
• 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 'What are possible side effects from using Levemir®?')
• In insulin infusion pumps.
• The Penfill® or Novo Nordisk Insulin Delivery Device containing the cartridge/FlexTouch® is dropped, damaged or crushed; there is a risk of leakage of insulin.
• The insulin has not been stored correctly or if it has been frozen (see “How to store Levemir®?”).
• The insulin does not appear water-clear and colourless.

Do not refill a Levemir® Penfill® cartridge.

Levemir® FlexTouch® is designed to be used with NovoFine®, NovoFine® Plus or NovoTwist® needles as part of The All In-One System®.

Levemir® Penfill® is designed to be used with Novo Nordisk Insulin Delivery Devices, NovoFine®, NovoFine® Plus or NovoTwist® 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 insulin delivery device in case the insulin delivery device is lost or damaged.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Levemir®. Talk about any health conditions or problems you may have, including if you:
• Have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid glands, your doctor may decide to alter your insulin dose.
• Drink alcohol (including wine and beer) your need for insulin may change as your blood sugar level may either rise or fall.
• Have an infection, fever or have had an operation you may need more insulin than usual.
• Suffer from diarrhea, vomiting or eat less than usual you may need less insulin than usual.
• Exercise more than usual or if you want to change your usual diet as this may affect your blood sugar level.
• Are ill: continue taking your insulin.
• Go abroad: travelling over time zones may affect your insulin needs and the timing of injections. Consult your doctor if you are planning such travel.
• Are pregnant, or planning a pregnancy please contact your doctor for advice when taking this medicine. Your insulin dose may need to be changed during pregnancy and after delivery. Careful control of your diabetes, and prevention of hypoglycemia, is important for the health of your baby.
• Are breast-feeding consult your doctor as you may require adjustments in your insulin doses.
• Have very low albumin you need to carefully monitor your blood sugar level. Discuss this with your doctor.
• Drive or use tools or machines: watch for signs of a hypoglycemia. Your ability to concentrate or to react will be less during a hypoglycemic reaction. Please keep this in mind in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). Never drive or use machinery if you feel a hypoglycemic reaction coming on.

Discuss with your doctor whether you should drive or use machines at all, if you have a lot of hypoglycemic reactions or if you find it hard to recognize hypoglycemias.

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.

Thiazolidinediones (class of oral antidiabetic drugs) used together with insulin may increase risk of oedema and heart failure. Inform your doctor as soon as possible if you experience localized swelling (oedema) or signs of heart failure such as unusual shortness of breath.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

The following may interact with Levemir®:
Some 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. Tell your doctor, Diabetes Nurse Educator or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription. In particular, you should tell your doctor if you are using any medicine as mentioned below that affects your blood sugar level.

If you take any of the medicines below, your blood sugar level may fall (hypoglycemia):
• Other medicines for the treatment of diabetes
• Monoamine oxidase inhibitors (MAOI) (used to treat depression)
• Beta-blockers (used to treat high blood pressure)
• Angiotensin converting enzyme (ACE) inhibitors (used to treat certain heart conditions or high blood pressure)
• Salicylates (used to relieve pain and lower fever)
• Anabolic steroids (such as testosterone)
• Sulphonamides (used to treat infections)

If you take any of the medicines below, your blood sugar level may rise (hyperglycemia):
• Oral contraceptives (birth control pills)
• Thiazides (used to treat high blood pressure or excessive fluid retention)
• Glucocorticoids (such as ‘cortisone’ used to treat inflammation)
• Thyroid hormones (used to treat thyroid gland disorders)
• Sympathomimetics (such as epinephrine [adrenaline], or salbutamol, terbutaline used to treat asthma)
• Growth hormone (medicine for stimulation of skeletal and somatic growth and pronounced influence on the body’s metabolic processes)
• Danazol (medicine acting on ovulation)
Octreotide and lanreotide (used for treatment of acromegaly, a rare hormonal disorder that usually occurs in middle-aged adults, caused by the pituitary gland producing excess growth hormone) may either increase or decrease your blood sugar level.

Beta-blockers (used to treat high blood pressure) may weaken or suppress entirely the first warning symptoms which help you to recognise a hypoglycemia.

**How to take insulin**

Levemir® is for injection under the skin (subcutaneously). Never inject your insulin directly into a vein or muscle. With each injection, change the injection site within the particular area of skin that you use. This may reduce the risk of developing lumps or skin pitting (see "What are possible side effects from using Levemir®?"). The best places to give yourself an injection are: the front of your thighs; the front of your waist (abdomen); or the upper arm. Your insulin will work more quickly if you inject around waist. You should always measure your blood glucose regularly.

Talk about your insulin needs with your doctor and Diabetes Nurse Educator. Do not change your insulin unless your doctor tells you to. 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). Do not 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.
- Always use new needle for each injection to prevent contamination [Penfill®/FlexTouch®].
- Do not share your Levemir® Penfill® in a Novo Nordisk Insulin Delivery Device/FlexTouch® with another person, even if the needle is changed. Do not reuse or share needles with another person including family members. You may give another person an infection or get an infection from them.

**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. Keep the push button fully depressed until the needle has been withdrawn. This will ensure correct delivery and limit possible flow of blood into the needle or insulin reservoir.
- After each injection be sure to remove the needle. Otherwise, the insulin may leak out when the temperature changes.

The injection can be given at any time during the day, but at the same time each day.

**Overdose**

**Causes of a hypoglycemia**

You get a hypoglycemia 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.

The warning signs of a hypoglycemia 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 hypoglycemia 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.

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 hypoglycemia in order to avoid getting more.

- If severe hypoglycemia is not treated, it can cause brain damage (temporary or permanent) and even death.
- If you have a hypoglycemia that makes you pass out, or if you get a lot of hypoglycemias, 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 hypoglycemic reactions in order to avoid getting more.

Causes of a hyperglycemia
You get a hyperglycemia if your blood sugar gets too high. This might happen:

- If you forget to take insulin.
- If you repeatedly take less insulin than you need.
- If you eat more than usual.
- If you exercise less than usual.

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.

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.

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.

If you think you have taken too much Leve\textsuperscript{r}mir\textsuperscript{®}, contact your health care practitioner, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.
What are possible side effects from using Levemir®?
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 ‘How to take Levemir®’. Also see ‘Overdose’ section.

Commonly reported side effects (1 to 10 users in 100)
Injection site reactions (pain, redness, hives, inflammation, bruising, swelling and itching) 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 (1 to 10 users in 1,000)

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 ‘Do not use Levemir® if’.

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 (lipodystrophy)
The fatty tissue under the skin at the injection site may shrink (lipoatrophy) or thicken (lipohypertrophy). Changing the site with each injection may help to reduce the risk of developing such skin changes. If you notice your skin pitting or thickening at the injection site, tell you 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 user in 10,000)

Disturbing sensations
Fast improvement in blood glucose control may cause disturbing sensations (n umbness, 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 you doctor, Diabetes Nurse Educator or your pharmacist.
Reporting Side Effects
You can help improve the safe use of health products for Canadians by reporting serious and unexpected side effects to Health Canada. Your report may help to identify new side effects and change the product safety information.

3 ways to report:
- Online at MedEffect (http://hc-sc.gc.ca/dhp-mps/medeff/index-eng.php);
- By calling 1-866-234-2345 (toll-free);
- By completing a Consumer Side Effect Reporting Form and sending it by:
  - Fax to 1-866-678-6789 (toll-free), or
  - Mail to: Canada Vigilance Program
    Health Canada, Postal Locator 1908C
    Ottawa, ON K1A 0K9


NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

How to store Levemir®?

Keep out of the reach and sight of children.

Before Opening: Levemir® that is not being used should be stored in the refrigerator between 2°C to 8°C, not in or too near the freezer section or cooling element. Do not freeze.

During use or when carried as a spare:
Levemir® FlexTouch®: You can carry your Levemir® FlexTouch® with you and keep it at temperatures below 30°C or in a refrigerator (2°C to 8°C). If refrigerated, keep away from the cooling element. Do not freeze. Use within 42 days.

Penfill®: Levemir® Penfill® that is being used or carried as a spare is not to be kept in the refrigerator. You can carry your Levemir® Penfill® with you and keep it at room temperature (below 30°C). Do not freeze. Use within 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.

FlexTouch®: Always keep the pen cap on your FlexTouch® when you’re 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.
What Levemir® looks like and package content
Levemir® Penfill® comes as a clear, colourless, aqueous solution of 5 cartridges of 3 mL per carton.
Levemir® FlexTouch® comes as a clear, colourless, aqueous solution in packages of 1 or 5 prefilled pens of 3 mL per cartons.

1 mL contains 100 U (units) of insulin detemir.
1 Penfill® cartridge contains 3 mL equivalent to 300 U.
1 prefilled pen contains 3 mL equivalent to 300 U.

If you want more information about Levemir®:
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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Instructions on how to use Levemir® 100 units/mL solution for injection in pre-filled pen (FlexTouch®).

Please read these instructions carefully before using your Levemir® FlexTouch® pre-filled pen. If you do not follow the instructions carefully, you may get too little or too much insulin, which can lead to too high or too low blood sugar.

Do not use the pen without proper training from your doctor or nurse. Start by checking your pen to make sure that it contains Levemir® 100 units/mL, then look at the illustrations to the right to get to know the different parts of your pen and needle.

If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help. Get help from a person with good eyesight who is trained to use the FlexTouch pre-filled pen.

Your Levemir® FlexTouch® pen is a prefilled insulin pen.

Levemir® FlexTouch® contains 300 units of insulin and delivers doses from 1 to 80 units, in increments of 1 unit.

Levemir® FlexTouch® is designed to be used with NovoFine® or NovoTwist® single-use disposable needles up to a length of 8 mm.

Do not share your Levemir® FlexTouch® with another person, even if the needle is changed. You may give another person an infection, or get an infection from them.
Preparing your Levemir® FlexTouch® pen

Check the name and coloured label on your Levemir® FlexTouch® pen to make sure that it contains the type of insulin you need. This is especially important if you take more than one type of insulin. If you take a wrong type of insulin, your blood sugar level may get too high or too low.

A  Pull off the pen cap.

B  Check that the insulin in your pen is clear and colourless. Look through the insulin window. If the insulin looks cloudy, do not use the pen.

C  Take a new disposable needle, and tear off the paper tab.
D Screw the needle straight onto the pen. Make sure the needle is on tight.

E Pull off the outer needle cap and save it. You will need it after the injection, to correctly remove the needle from the pen. Pull off the inner needle cap and throw it away. If you try to put it back on, you may accidentally stick yourself with the needle. A drop of insulin may appear at the needle tip. This is normal.

⚠️ Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing. Do not reuse or share needles with another person including family members. ⚠️ Never bend or damage the needle.

Checking the insulin flow

Make sure that you receive your full dose by always checking the insulin flow before you select and inject your dose.

F Turn the dose selector to select 2 units.
G  Hold the pen with the needle pointing up.
    Tap the top of the pen a few times to let any air bubbles rise to the top.

H  Press the dose button with your thumb until the dose counter returns to 0. The 0 must line
    up with the dose pointer. A drop of insulin will appear at the needle tip.

    If no drop appears, repeat steps F to H up to 6 times. If no drop appears after these new
    attempts, change the needle and repeat steps F to H once more.

    Do not use the pen if a drop of insulin still does not appear.

⚠️ Always make sure that a drop appears at the needle tip before you inject. This
    makes sure that the insulin flows. If no drop appears, you will not inject any insulin,
    even though the dose counter may move. This may indicate a blocked or damaged
    needle.

⚠️ Always check the flow before you inject. If you do not check the flow, you may get
    too little insulin or no insulin at all. This may lead to too high blood sugar level.

Selecting your dose
Use the dose selector on your Levemir® FlexTouch® pen to select your dose. You can
select up to 80 units per dose.

I  Select the dose you need. You can turn the dose selector forwards or backwards. Stop
    when the right number of units lines up with the dose pointer.
The dose selector clicks differently when turned forwards, backwards or past the number of units left.

When the pen contains less than 80 units, the dose counter stops at the number of units left.

Always use the dose counter and the dose pointer to see how many units you have selected before injecting the insulin.

Do not count the pen clicks. If you select and inject the wrong dose, your blood sugar level may get too high or too low.

Do not use the insulin scale, it only shows approximately how much insulin is left in your pen.

⚠️ How much insulin is left?

The **insulin scale** shows you **approximately** how much insulin is left in your pen.

⚠️ **Be very careful to calculate correctly if splitting your dose.**

If in doubt, take the full dose with a new pen. If you split the dose wrong, you will inject

**To see approximately how much insulin is left** use the dose counter.

Turn the dose selector until the **dose counter stops**. If it shows 80, **at least 80** units are left in your pen.

If it shows **less than** 80, the number shown is the number of units left in your pen.

Turn the dose selector back until the dose counter shows 0.
If you need more insulin than the units left in your pen, you can split your dose between two pens.

**Injecting your dose**

**Make sure that you receive your full dose by using the right injection technique.**

1. Insert the needle into your skin as your doctor or Diabetes Nurse Educator has shown you. Make sure you can see the dose counter. Do not touch the dose counter with your fingers. This could interrupt the injection.

2. Press the dose button until the dose counter returns to zero. The 0 must line up with the pointer. You may then hear or feel a click.

3. After the dose counter has returned to 0, leave the needle under the skin for **at least 6 seconds** to make sure that you get your full dose.

4. Remove the needle from the skin.

After that, you may see a drop of insulin at the needle tip. This is normal and has no effect on the dose you just received.
Always dispose of the needle after each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles, and inaccurate dosing. If the needle is blocked, you will not inject any insulin.

Lead the needle tip into the outer needle cap on a flat surface. Do not touch the needle or the cap.

Once the needle is covered, carefully push the outer needle cap completely on and then unscrew the needle. Dispose of it carefully, and put the pen cap back on after every use.

When the pen is empty, throw it away without a needle on as instructed by your doctor, Diabetes Nurse Educator or local authorities.

Always watch the dose counter to know how many units you inject. The dose counter will show the exact number of units.

Do not count the pen clicks.

Hold the dose button down until the dose counter returns to 0 after the injection. If the dose counter stops before it returns to 0, the full dose has not been delivered, which may result in too high blood sugar level.

Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.

Always remove the needle after each injection and store your pen without the needle attached. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

Caring for your pen

Treat your pen with care. Rough handling or misuse may cause inaccurate dosing, which can lead to too high or too low blood sugar level.

- Do not leave the pen in a car or other place where it can get too hot or too cold.
- Do not expose your pen to dust, dirt, or liquid.
• **Do not wash, soak or lubricate your pen.** If necessary, clean it with mild detergent on a moistened cloth.
• **Do not drop your pen** or knock it against hard surfaces. If you drop it or suspect a problem, attach a new needle and check the insulin flow before you inject.
• **Do not try to refill your pen.** Once empty, it must be disposed of.
• Do not try to repair your pen or pull it apart.

⚠ **Important Information**

• **Always carry an extra pen and new needles** with you, in case of loss or damage to your current pen.
• Always keep your pen and needles **out of sight and reach of others, especially children.**
• **Never share** your pen or your needles with other people. It might lead to cross infection.
• **Never share** your pen with other people. Your medicine might be harmful to their health.
• Caregivers must be **very careful when handling used needles** to reduce the risk of needle injury and cross-infection.