

Levemir® FlexPen®

Consumer Medication Information Leaflet (RIMUP)

Insulin Detemir (100U/ml)

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What Levemir® is used for

Levemir® is used to treat diabetes mellitus. Diabetes mellitus is a disease where your body does not produce enough insulin to control the level of your blood sugar.

How Levemir® works

Levemir® is a modern insulin (insulin analogue) with a long-acting effect (up to 24 hours). Modern insulins are improved versions of human insulin. It may be used in combination with oral antidiabetic medicines or with meal-related rapid-acting insulin products. Compared to other insulins, therapy with Levemir® is associated with less weight gain.

Before you use Levemir®

-When you must not use it

- ▶ **If you are allergic (hypersensitive)** to insulin detemir or any of the other ingredients in Levemir®
- ▶ **If you suspect hypoglycaemia (low blood sugar)** is starting
- ▶ **In insulin infusion pumps.**
- ▶ **If FlexPen® is dropped, damaged or crushed.**
- ▶ **If it has not been stored correctly** or if it has been frozen
- ▶ **If the insulin does not appear water clear and colourless.**

-Before you start to use it

- ▶ **Check the label to make sure** it is the right type of insulin.
- ▶ **Always use a new needle** for each injection to prevent contamination.
- ▶ **Needles and Levemir® FlexPen® must not be shared.**

-Taking other medicines

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, nurse 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 mentioned below that may affect your blood sugar level.

If you take any of the medicines below, your blood sugar level may fall (hypoglycaemia):

- 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)

If you take any of the medicines below, your blood sugar level may rise (hyperglycaemia):

- 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 hypoglycaemia.

How to use Levemir®

-How much to use

Talk about your insulin needs with your doctor and nurse. Follow their advice carefully. 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.

-When to use it

When Levemir® is used in combination with an oral antidiabetic medicine, Levemir® should be administered once a day. When Levemir® is used as part of a basal-bolus insulin regimen, Levemir® should be administered once or twice daily depending on patients' needs. Dosage of Levemir® should be adjusted individually. The injection can be given at any time during the day, but at the same time each day. For patients who require twice daily dosing to optimise blood glucose control, the evening dose can be administered in the evening or at bedtime.

-How long to use it

Talk about your insulin needs with your doctor or nurse. Do not change your insulin unless your doctor tells you to. Make sure you get the colour-coded Levemir® FlexPen® as your doctor and nurse have told you to use and follow their advice carefully.

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.

-If you forget to use it

If you forget to take your insulin, your blood sugar may get too high (this is called hyperglycaemia). This may also happen:

- If you repeatedly take less insulin than you need.
- If you get an infection or a fever.
- 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; dry mouth and a fruity (acetone) smell of the breath.

These may be signs of a very serious condition called diabetic ketoacidosis (build-up of acid in the blood because the body is breaking down fat instead of sugar). If you do not treat it, this could lead to diabetic coma and eventually death.

If you get any of these signs mentioned above, test your blood sugar level, test your urine for ketones if you can, then seek medical advice immediately.

-If you use too much (overdose)

If you take too much insulin, your blood sugar gets too low (this is called hypoglycaemia or hypo). This may also happen:

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

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; difficulty in concentrating. If you feel a hypo coming on, take a high sugar snack and then measure your blood sugar. If your blood sugar is too low, eat glucose tablets or another high sugar snack (sweets, biscuits, fruit juice), then rest.

Always carry glucose tablets, sweets, biscuits or fruit juice with you, just in case.

While you are using it

-Things you must do

Levemir® is for injection under the skin (subcutaneously). Never inject your insulin directly into a vein (intravenously) or muscle (intramuscular). 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. 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 sugar regularly

-Things you must not do

Do not 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 seek medical advice straight away. They **must not** give you any food or drink as it could choke you.

-Things to be careful of

If you drive or use tools or machines, watch out 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 can drive or use machines at all, if you have a lot

of hypos or if you find it hard to recognise hypos.

Side effects

Side effects may occur with certain frequencies, which are defined as follows:

- Very common: affects more than 1 user in 10
- Common: affects 1 to 10 users in 100
- Uncommon: affects 1 to 10 users in 1,000
- Rare: affects 1 to 10 users in 10,000
- Very rare: affects less than 1 user in 10,000
- Not known: frequency cannot be estimated from the available data

Common side effects

Hypoglycaemia

Injection site reactions (pain, redness, hives, inflammation, bruising, swelling and itching). 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.

Uncommon side effects

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 in breathing; have a rapid heart beat; feel dizzy.

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 your doctor or nurse. These reactions can become more severe, or they may change the absorption of your insulin, if you inject in such a site.

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

Diabetic retinopathy (an eye disease related to diabetes which can lead to loss of vision). If you have diabetic retinopathy and your blood sugar level improve abruptly, the retinopathy may get worse temporary. Ask your doctor about this.

Rare side effects

Painful neuropathy (pain due to nerve damage). If your blood sugar level improve very fast, you may get nerve related pain, this is called acute painful neuropathy and is usually transient.

Very rare side effects

Serious allergic reaction to Levemir® or one of its ingredients (called a systemic allergic reaction). If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers → Reporting).

Storage and Disposal of Levemir®

-Storage

Levemir® FlexPen® that is not being used is to be stored in the refrigerator at 2°C-8°C, away from the cooling element. Do not freeze. **Levemir® FlexPen® that is being used** or carried as a spare is not to be kept in the refrigerator. You can

carry it with you and keep it at room temperature (below 30°C) for up to 6 weeks.

Always keep the pen cap on your FlexPen® when you are not using it in order to protect it from light.

Levemir® must be protected from excessive heat and light.

Keep out of the reach and sight of children.

-Disposal

Do not use Levemir® after the expiry date which is stated on the label and the carton after 'Expiry'. The expiry date refers to the last day of that month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description

-What it looks like

Levemir® comes as a clear, colourless, aqueous solution

-Ingredients

-Active ingredient
insulin detemir

-Inactive ingredients
glycerol, phenol, metacresol, zinc acetate, disodium phosphate dihydrate, sodium chloride, hydrochloric acid, sodium hydroxide and water for injections.

-MAL number:

MAL20061574A

Manufacturer

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

Product Registration Holder

Novo Nordisk Pharma (M) Sdn Bhd
Unit A-9-2, Level 9, Tower A
Menara UOA Bangsar
No.5 Jalan Bangsar Utama 1
59000 Kuala Lumpur, Malaysia

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