Levemir® FlexPen®

Insulin detemir (rys)

Consumer Medicine Information

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This leaflet answers some common questions about Levemir® FlexPen®. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Levemir® FlexPen® against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor, diabetes education nurse or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Levemir® is used for

The insulin detemir (rys), or “Levemir®”, in Levemir® FlexPen® is a long-acting insulin used to treat diabetes mellitus. It may be used in combination with oral antidiabetic medicines (diabetes tablets) or as add-on therapy to liraglutide (Victoza®), which is used to treat type 2 diabetes mellitus in adults. Levemir® can also be used with a meal-related short- or rapid-acting insulin such as NovoRapid®.

Diabetes mellitus is a condition where your pancreas does not produce enough insulin to control your blood sugar (glucose) level. Extra insulin is therefore needed.

There are two types of diabetes mellitus:

Type 1 diabetes – also called juvenile onset diabetes
Type 2 diabetes – also called maturity onset diabetes

Patients with type 1 diabetes always require insulin to control their blood sugar levels.

Some patients with type 2 diabetes may also require insulin after initial treatment with diet, exercise and tablets.

Levemir® lowers your blood sugar level after injection. The effect may last for up to 24 hours.

As with all insulins, the duration of action will vary according to the dose, injection site, blood flow, temperature and level of physical activity.

FlexPen® is a pre-filled dial-a-dose insulin pen able to deliver from 1 to 60 units of Levemir® in increments of 1 unit.

This medicine is not addictive.

Levemir® FlexPen® is available only with a doctor’s prescription.

Ask your doctor, diabetes education nurse or pharmacist if you have any questions about why this medicine has been prescribed for you.

Before you use Levemir® FlexPen®

When you must not use it

Do not use this medicine if:

1. you have an allergy to:
   • any medicine containing insulin
   • any of the ingredients listed in the ‘Ingredients’ section of this leaflet.
   Some of the symptoms of an allergic reaction may include:
   • redness, swelling, rash and itching at the injection site;
   • rash, itching or hives on the skin;
   • shortness of breath;
   • wheezing or difficulty breathing;
   • swelling of the face, lips, tongue or other parts of the body.

2. you are experiencing low blood sugar levels (a “hypo”) when your dose is due.
   If you have a lot of hypos discuss appropriate treatment with your doctor.

If you are not sure whether you should start using this medicine, talk to your doctor.

Do not use this medicine after the expiry date printed on the pack, or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to use it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.
Tell your doctor if you have or have had any of the following medical conditions:

- kidney problems
- liver problems
- adrenal, pituitary or thyroid gland problems

Tell your doctor if you are pregnant or plan to become pregnant.

Pregnancy may make managing your diabetes more difficult. Insulin needs usually decrease during the first three months of pregnancy and increase during the last six months. Your doctor can discuss with you the risks and benefits involved.

Tell your doctor if you are breast-feeding or plan to breast-feed.

Your doctor can discuss with you the risks and benefits involved.

Inform your doctor as soon as possible if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who are treated with thiazolidinediones in combination with insulin may develop heart failure.

If you have not told your doctor about any of the above, tell them before you start using this medicine.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or health food shop. Some medicines and Levemir® may interfere with each other. These include:

- oral antidiabetic medicines - used to treat type 2 diabetes
- monoamine oxidase inhibitors (MAOI) - used for the treatment of depression
- alpha blockers - used to treat high blood pressure and to relieve difficulty in passing urine caused by an enlarged prostate
- non-selective beta blockers – used to treat high blood pressure and certain heart conditions
- ACE inhibitors - used to treat high blood pressure, certain heart conditions or elevated protein/albumin in the urine
- salicylates e.g. aspirin - used to relieve pain and lower fever
- anabolic steroids – used to promote growth
- glucocorticoids (except when applied locally) – used to treat inflammatory conditions
- oral contraceptives (“the pill”) - used for birth control
- diuretics e.g. thiazides, frusemide or ethacrynic acid - used to treat high blood pressure or fluid retention (oedema)
- thyroid hormones - used to treat malfunction of the thyroid gland
- sympathomimetics - used to treat asthma
- sulphonamides – used to treat bacterial infections

Or other specific medicines including:

- danazol - used to treat endometriosis, menorrhagia, fibrocystic breast disease and hereditary angioedema
- oxymetholone – used to treat certain blood disorders
- octreotide - used to treat gastrointestinal endocrine tumours and enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal growth hormone levels
- lanreotide – used to treat enlargement of parts of the body (e.g. hands, feet, head) caused by abnormal hormone levels
- diazoxide - used to treat high blood pressure
- nicotinic acid - used to treat high cholesterol levels in the blood
- asparaginase - used to treat leukaemia and lymph gland tumours
- quinine – used to treat malaria and relieve muscle cramps
- quinidine – used to treat heart problems
- growth hormone – used to treat growth disorders

Tell your doctor about any other medicines that you are taking.

This is very important. Your doctor will advise you if it is alright to keep taking them or if you should stop taking them.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

**How to use Levemir® FlexPen®**

Your doctor, diabetes education nurse or pharmacist will have given you advice on how to use your medicine. Carefully follow all the directions.

They may differ from the information contained in this leaflet.

Any change in dose or type of insulin should be made cautiously and only under medical supervision.

If you change the type of insulin that you use, you may have to use more or less than before. This may happen with the first dose or over a period of time.

If you do not understand the instructions, ask your doctor, diabetes education nurse or pharmacist for help.

**How much to use**

Your doctor or diabetes education nurse will tell you how much of this medicine you need to use.

It is very important that you manage your diabetes carefully. Too much or too little insulin can cause serious effects.
**When to use it**

Levemir® is either injected once or twice daily. If you require twice daily dosing, the evening dose can be administered either with the evening meal, at bedtime, or 12 hours after the morning dose. Your doctor will tell you when to inject your medicine.

**How to use it**

- Inject Levemir® under the skin (subcutaneous injection) as shown to you by your doctor or diabetes education nurse. **Never inject Levemir® directly into a vein or muscle.**
- Levemir® may be injected into your abdomen, thigh, buttock or upper arm.
- Remember to change your injection site regularly as shown to you by your doctor or diabetes education nurse.
- Do not use Levemir® in insulin pumps.

**Checking your Levemir® FlexPen®**

Check your medicine before each preparation and injection. Make sure you are using the correct type of insulin.

Levemir® is a clear colourless solution. Do not use this medicine if it is thickened, coloured, or has solid bits in it.

Read the instructions printed later in this leaflet carefully in order to prepare and handle your Levemir® FlexPen® correctly.

**How long to use it**

Do not stop using Levemir® FlexPen® unless your doctor tells you to.

**If you use too much (overdose) – Hypoglycaemia**

Your blood sugar level may become too low (you may experience hypoglycaemia or a “hypo”) if you:
- use too much insulin
- miss a meal
- exercise more than usual
- are ill

The first symptoms of mild to moderate hypos can come on suddenly. They may include:
- cold sweat, cool pale skin
- fatigue, drowsiness, unusual tiredness and weakness
- nervousness, anxious feeling, tremor, rapid heart beat
- confusion, difficulty concentrating
- excessive hunger
- vision changes
- headache, nausea

**Always carry some sugary food or fruit juice with you.**

If you experience any of these symptoms of a hypo, immediately eat some sugary food or have a sugary drink, e.g. lollies, biscuits or fruit juice, and measure your blood sugar level.

Tell your relatives, friends, close workmates or carers that you have diabetes. It is important that they recognise the signs and symptoms of a hypo.

**Make sure they know to give you some sugary food or fruit juice for mild to moderate symptoms of a hypo.**

If you lose consciousness, make sure they know:
- to turn you on your side and get medical help immediately
- not to give you anything to eat or drink

This is because you could choke.

An injection of the hormone glucagon may speed up recovery from unconsciousness. This can be given by a relative, friend, workmate or carer who knows how to give it.

If glucagon is used, eat some sugary food or have a sugary drink as soon as you are conscious again.

**If you do not respond to glucagon treatment, you will have to be treated in a hospital.**

See your doctor if you keep having hypo reactions, or if you have ever become unconscious after using insulin.

The amount or timing of insulin, food or exercise may need to be adjusted.

If a prolonged, severe hypo is not treated it can cause brain damage and death.

**If you miss a dose – Hyperglycaemia**

If you forget your insulin dose, check your blood sugar level and test your urine for ketones as soon as possible.

If you are not sure what to do, talk to your doctor, diabetes education nurse or pharmacist.

Do not use a double dose of your insulin.

If it is almost time for your next dose, skip the dose you missed and use your next dose when you are meant to.

Otherwise, use it as soon as you remember, and then go back to using it as you would normally.

Your blood sugar levels may become high (hyperglycaemia) if you:
- miss doses of insulin or use less insulin than you need
- have uncontrolled diabetes
- exercise less than usual
- eat more carbohydrates than usual
- are ill or stressed

High blood sugar levels over a long period of time can lead to too much acid in the blood (diabetic ketoacidosis).

Contact your doctor immediately if your blood sugar level is high or you recognise any of the following symptoms.
Symptoms of mild to moderate hyperglycaemia include:
- drowsy feeling
- flushed face
- thirst, loss of appetite
- fruity odour on the breath, dry mouth
- blurred vision
- passing larger amounts of urine than usual
- getting up at night more often than usual to pass urine
- high levels of glucose and acetone in the urine

Symptoms of severe hyperglycaemia include:
- heavy breathing
- fast pulse
- nausea, vomiting
- dehydration
- loss of consciousness

Severe hyperglycaemia can lead to unconsciousness and in extreme cases death if untreated.

Discuss any worries you may have about this with your doctor, diabetes education nurse or pharmacist.

While you are using Levemir® FlexPen®

Things you must do

Measure your blood sugar level regularly.

Make sure all friends, relatives, workmates and carers know that you have diabetes and are using insulin.

If your child has diabetes it is important to tell their carers.

Keep using your insulin even if you feel well.

It helps to control your condition, but does not cure it.

Tell your doctor if you often have hypos (low blood sugar levels).

Your doctor may need to adjust your insulin dose.

Always carry some sugary food or fruit juice with you.

If you experience any of the symptoms of a hypo, immediately eat some sugary food or have a drink, e.g. lollies, biscuits or fruit juice, and measure your blood sugar level.

Tell your doctor if you have trouble recognising the symptoms of hypos.

Under certain conditions, the early warning signs of hypos can be different or less obvious. Your doctor may need to adjust your insulin dose.

Make sure that you tell every doctor, dentist, pharmacist or other health care professional who is treating you that you have diabetes and are using insulin.

Tell your doctor, diabetes education nurse or pharmacist if you are travelling.

Ask them for a letter explaining why you are taking injecting devices with you. Each country you visit will need to see this letter, so you should take several copies.

You may need to inject your insulin and eat your meals at different times because of time differences in and between countries.

You may not be able to get the same type of insulin in the country you are visiting.

Your doctor, diabetes education nurse or pharmacist can provide you with some helpful information.

Things you must not do

Do not stop using Levemir® FlexPen® unless your doctor tells you to.

Do not use this medicine if you think it has been frozen or exposed to excessive heat.

It will not work as well.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not share needles.

Things to be careful of

Be careful driving or operating machinery until you know how the insulin affects you.

If your blood sugar is low or high your concentration and ability to react might be affected and therefore also your ability to drive or operate a machine. Bear in mind that you could endanger yourself or others. Please ask your doctor whether you can drive a car:
- if you have frequent hypos
- if you find it hard to recognise hypos

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypos. If you are drinking alcohol your need for insulin may change, as your blood sugar level may either rise or fall. Careful monitoring is recommended.

Tell your doctor if you are ill.

Illness, especially with nausea and vomiting, may cause your insulin needs to change. Even if you are not eating, you still require insulin. You and your doctor should design an insulin plan for those times when you are sick.

Tell your doctor if you are exercising more than usual.

Exercise may lower your need for this medicine. Exercise may also speed up the effect of a dose of it, especially if the exercise involves the area of the injection site (e.g. the leg should not be used for injection prior to jogging or running).

Tell your doctor if your diet changes.

Insulin is essential to keep your blood sugar levels within acceptable limits. Regular meals and a balanced diet are important factors in the management of diabetes. It is
important that you discuss a suitable
diet plan with your doctor or
diabetes team.

Smoking may increase the chance of
complications with your diabetes.

Side effects

Tell your doctor, diabetes
education nurse or pharmacist as
soon as possible if you do not feel
well while you are using Levemir®
FlexPen®.

This medicine helps most people for
whom it is prescribed, but it may
have unwanted side effects in a few
people. All medicines can have side
effects. Sometimes they are serious,
most of the time they are not. You
may need medical treatment if you
get some of the side effects.

Do not be alarmed by the following
lists of side effects. You may not
experience any of them.

Ask your doctor, diabetes
education nurse or pharmacist to
answer any questions you may
have.

The most common side effect when
using insulin is low blood sugar
levels (a hypo).

Tell your doctor if you notice any
of the following and they worry
you:

- hypos (mild to moderate)
- pain, redness, swelling, hives,
inflammation, bruising or
itching at the injection site.

Usually these symptoms
disappear within a few weeks
during continued use. If you
have serious or continuing
reactions, you may need to stop
using Levemir® and use another
insulin.

- a depression or thickening of the
skin around the injection site
(lipodystrophy)
- when you first start your insulin
treatment you may get visual
problems or swollen hands and
feet

This list includes the more common
side effects of your medicine. They
are usually mild and short-lived.

If any of the following happen, tell
your doctor immediately or go to
Accident and Emergency at your
nearest hospital:

- skin rashes over a large part of
the body
- shortness of breath, wheezing
- swelling of the face, lips or
tongue
- fast pulse
- sweating

If a severe hypo is not treated, it can
cause brain damage and death.

Tell your doctor immediately or
go to Accident and Emergency at
your nearest hospital if you notice
any of the following:

- disorientation
- seizures, fits or convulsions
- loss of consciousness

Tell your doctor if you notice
anything that is making you feel
unwell.

Other side effects not listed above
may also occur in some people.

Ask your doctor, diabetes
education nurse or pharmacist to
answer any questions you have.

After using Levemir®
FlexPen®

Storage

Store Levemir® FlexPen® that are
not being used between 2°C and
8°C in a refrigerator (not in or too
near the freezer section or cooling
element).

Do not keep the Levemir®
FlexPen® that are carrying as a spare,
in a refrigerator.

You can use it up to 4 weeks at or
below 30°C after taking it out of the
refrigerator.

Discard Levemir® FlexPen® after
4 weeks even if there is still some
medicine left in it.

The Levemir® in Levemir®
FlexPen® must not be frozen, or
exposed to excessive heat or light.
Protect the medicine in Levemir®
FlexPen® from light by keeping the
pen cap on when not in use.

Do not use Levemir® after the expiry
date which is stated on the FlexPen®
label and carton after ‘Expiry’.

Never use Levemir® FlexPen® if
the solution is not clear and
colourless.

Keep out of the reach of children.

Disposal

Dispose of used needles safely into
a sharps container.

If your doctor tells you to stop using
this medicine or the expiry date has
passed, ask your pharmacist what to
do with any medicine that is left
over.

Product description

What it looks like

Levemir® is a clear, colourless,
aqueous solution for subcutaneous
injection. Levemir® FlexPen® is a
3mL pre-filled glass cartridge
contained in a dial-a-dose insulin
pen.

Ingredients

Levemir® contains insulin detemir
(rys) 100 units per mL (100 U/mL)
as the active ingredient. The
abbreviation “rys” indicates the
method of genetic engineering used
to manufacture this insulin.

Levemir® also contains the
following inactive ingredients:

- glycerol
- phenol
- meta-cresol
- zinc acetate
- sodium chloride
- dibasic sodium phosphate dihydrate
- sodium hydroxide
- hydrochloric acid
- water for injections
Sponsor

Levemir® FlexPen® is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty. Ltd.

Level 3, 21 Solent Circuit
Baulkham Hills
NSW 2153
Australia

Levemir® FlexPen® is supplied in New Zealand by:

Novo Nordisk Pharmaceuticals Ltd.

58 Richard Pearse Drive
Airport Oaks
Mangere
New Zealand

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Further information

For further information call the NovoCare® Customer Care Centre on 1800 668 626 (Australia) or 0800 733 737 (NZ).

www.novonordisk.com.au
www.novonordisk.co.nz

You can also get more information about diabetes and insulin from Diabetes Australia and Diabetes New Zealand:

- freecall helpline 1300 136 588 (Australia)
- www.diabetesaustralia.com.au
- www.diabetes.org.nz
Instructions For Use

Introduction

Please read the following instructions carefully before using your Levemir® FlexPen®.

Your Levemir® FlexPen® is a unique, dial-a-dose insulin pen. You can select doses from 1 to 60 units in increments of 1 unit. FlexPen® is designed to be used with NovoFine® or NovoTwist® disposable needles up to a length of 8mm.

As a precautionary measure, always carry a spare insulin delivery device in case your FlexPen® is lost or damaged.

Maintenance

Your FlexPen® is designed to work accurately and safely. It must be handled with care. If it is dropped or crushed, there is a risk of damage and leakage of insulin.

You can clean the exterior of your FlexPen® by wiping it with an alcohol swab. Do not soak it, wash or lubricate it as this may damage the pen.

Do not refill your FlexPen®.

Preparing your Levemir® FlexPen®

Check the label to make sure that your FlexPen® contains the correct type of insulin.

A

Pull off the pen cap.

B

Remove the paper tab from a NovoFine® or NovoTwist® disposable needle.

If using a NovoFine® needle screw the needle onto your FlexPen® so that it is straight and secure. If using a NovoTwist® needle, twist the needle onto your FlexPen® until a "click" is heard.
C
Pull off the big outer needle cap and keep it for later.

D
Pull off the inner needle cap and dispose of it.

- Always use a new needle for each injection to prevent contamination.
- Be careful not to bend or damage the needle before use.
- To reduce the risk of needlestick injury, **never** put the inner needle cap back on once you have removed it from the needle.

**Checking the insulin flow**

It is important to prime your FlexPen® prior to every injection. The priming procedure may highlight a malfunction with FlexPen®. Priming also removes any air bubbles and would help indicate whether or not a needle is blocked. If problems are encountered during priming, use an alternative insulin delivery system, **DO NOT USE YOUR FLEXPEN®**, and contact your diabetes education nurse and/or Novo Nordisk. To prime your FlexPen®:

E
Turn the dose selector to select 2 units.

F
Hold your FlexPen® with the needle pointing upwards and tap the cartridge gently with your finger a few times to make any air bubbles collect at the top of the cartridge.
Keeping the needle upwards, press the push-button all the way in. The dose selector returns to 0.

A drop of insulin should appear at the needle tip. If not, change the needle and repeat the procedure no more than six times.

If a drop of insulin still does not appear, your FlexPen® has failed to prime, and you must use a new one.

Selecting your dose

Check that the dose selector is set at 0.

Turn the dose selector to select the number of units you need to inject. Do not use the residual scale to measure your dose of insulin.

The dose can be corrected either up or down by turning the dose selector in either direction until the correct dose lines up with the pointer. When turning the dose selector, be careful not to push the push-button as insulin will come out.

You cannot select a dose larger than the number of units left in the cartridge.
Injecting the insulin

Insert the needle into your skin. Use the injection technique shown by your doctor or diabetes education nurse.

I
Inject the dose by pressing the push-button all the way in until 0 lines up with the pointer. Be careful to only push the push-button when injecting. Turning the dose selector will not inject insulin.

J
Keep the push-button fully depressed after the injection until the needle has been withdrawn from the skin. The needle must remain under the skin for at least six seconds. This will ensure that the full dose has been injected.

K
Guide the needle into the big outer needle cap without touching the big outer needle cap, as shown. When the needle is covered, carefully push the big outer needle cap completely on and then remove the needle by unscrewing it (for NovoFine® needles) or with a twist (for NovoTwist® needles).

Dispose of it carefully and put the pen cap back on.

- Always remove the needle after each injection and store your FlexPen® without the needle attached. Otherwise, the liquid may leak out, which can cause inaccurate dosing.
- Health care professionals, relatives and other carers should follow general precautionary measures for removal and disposal of needles, to eliminate the risk of needlestick injury.
- Dispose of your used FlexPen® carefully, without the needle attached.
- Do not share your FlexPen® with anyone else.