**PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

**S3**

**Levemir® solution for Injection**
Insulin detemir 100 U/mL
Sugar free.

**Read all of this leaflet carefully before you start using Levemir®**
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Levemir® has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

**What is in this leaflet**


1. What Levemir® is and what it is used for.
2. What you need to know before you use Levemir®.
3. How to use Levemir®.
4. Possible side effects.
5. How to store Levemir®.
6. Contents of the pack and other information.


## 1. What Levemir® is and what it is used for

Levemir® is used to treat diabetes mellitus (high blood sugar) in adults and children aged 1 year and older.

## 2. What you need to know before you use Levemir®

***You should not administer Levemir®:***
- If you are allergic (hypersensitive) to insulin detemir or any of the other ingredients in Levemir® (see section 6).
- If your blood sugar level is low (hypoglycaemia).
- If you suspect hypoglycaemia (low blood sugar) is starting (see section 3).
- In insulin infusion pumps.
- If the cartridge or the device containing the cartridge is dropped, damaged or crushed.
- If it has not been stored correctly or if it has been frozen (see section 5).
- If the insulin does not appear water clear and colourless.

**Levemir® should not be administered into a vein**.

**Before you administer Levemir®**
- Check the label to make sure it is the right type of insulin.
- Penfill®: Always check the cartridge, including the rubber plunger (stopper).
  Do not use it if any damage is seen or if there is a gap between the rubber plunger and the white label band. Take it back to your supplier. See your delivery system manual for further instructions.
- Always use a new needle for each injection to prevent contamination.
- Needles and Levemir® Penfill®/FlexPen®/PenSet must not be shared.

**Warnings and precautions**
**Take special care with Levemir®**
- If you have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid glands.
- If you exercise more than usual or if you want to change your usual diet, as this may affect your blood sugar level.
- If you are ill, carry on using your insulin and consult your doctor.
- If you are going abroad: travelling over time zones may affect your insulin needs and the timing of your injections. Consult your doctor if you are planning such travelling.
- If you are changing the type of insulin you are using. Talk to your doctor before you start using Levemir®.

- If you have very low albumin you need to carefully monitor your blood sugar level. Discuss this with your doctor.

**Skin changes at the injection site**
The injection site should be rotated to help prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin. Levemir® may not work very well if you inject into a lumpy, shrunken or thickened area (see section 3). Tell your doctor if you notice any skin changes at the injection site. Tell your doctor if you are currently injecting into these affected areas before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medicine dose.

**Children and adolescents**
Levemir® can be used in adolescents and children aged 1 year and above.
The safety and efficacy of Levemir® in children below 1 year of age have not been established. No data are available.

**Other medicines and Levemir®**
***Always tell your health care provider if you are taking any other medicines. (This includes complementary or traditional 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, pharmacist or other health care provider 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 (hypoglycaemia):**
- Other medicines for the treatment of diabetes
- Monoamine oxidase inhibitors (MAOI) (used to treat depression) including linezolid (use to treat bacterial infections).
- Beta-blockers (used to treat high blood pressure), angiotensin receptor blockers ARBs (used to treat certain heart conditions or high blood pressure) and renin antagonists such as aliskiren (used to treat high blood pressure)
- Angiotensin converting enzyme (ACE)-inhibitors (used to treat certain heart conditions or high blood pressure)
- Aspirin (used to relieve pain and lower fever)
- Aliskiren (used to treat high blood pressure)
- Anabolic steroids (such as testosterone)
- Sulphonamides (used to treat infections)

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

Somatostatin analogues such octreotide, lanreotide and pasireotide (used for treatment of acromegaly, may either increase or decrease your blood sugar level.

Beta-blockers (used to treat high blood pressure) may suppress the warning symptoms which help you to recognise low blood sugar (hypoglycaemia) and may prevent the body’s normal response/reaction to low blood sugar.

Pioglitazone (class of oral antidiabetic medicines used for the treatment of type 2 diabetes mellitus). Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke who are treated with pioglitazone in combination with insulin may develop heart failure. 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).

**Levemir® with food, drink and alcohol**
If you drink alcohol, your need for insulin may change, as your blood sugar level may either rise or fall. Careful monitoring is recommended.

**Pregnancy, breastfeeding and fertility**
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking Levemir®.
Your insulin dose may need to be changed during pregnancy and after delivery. Careful control of your diabetes, particularly prevention of hypoglycaemia, is important for the health of your baby.
If you are breastfeeding consult your doctor as you may require adjustments in your insulin doses and/or your diet.

Ask your doctor or pharmacist or other health care provider for advice before administering Levemir® if you are pregnant or breastfeeding.

**Driving and using machines**
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.
Please ask your doctor whether you can drive a car:
- If you frequently get low blood sugar (hypoglycaemia).
- If you find it hard to know when your sugar gets low (hypoglycaemia)

## 3. How to use Levemir®

**This medicine has been 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.**
Always administer Levemir® exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

**Dosage**
Talk about your insulin needs with your doctor, pharmacist or other health care provider. Do not change your insulin unless your doctor tells you to.

Penfill®/FlexPen®: Make sure you use Levemir® Penfill®/FlexPen® as your doctor or pharmacist or other health care provider have instructed you and follow their advice carefully.

If your doctor has switched you from one type or brand of insulin to another, or if your doctor has added another medicines for the treatment of diabetes in addition to your Levemir®, your dose may have to be adjusted by your doctor.
**Use in children**
Levemir® can be used in adolescents and children aged 1 years and above.
There is no experience with the use of Levemir® in children below the age of 1 years.

**Use in special populations**
If you have reduced kidney or liver function, or if you are above 65 years of age, you need to check your blood sugar more regularly and discuss changes in your insulin dose with your doctor.

**Frequency of administration**
When Levemir® is used in combination with an oral antidiabetic medicine or as add-on therapy to injectable 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. The dose 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.

**Method of administration**
Levemir® is for injection under the skin (subcutaneously). You must 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 (see section 4). The best places to give yourself an injection are: the front of your thighs, your buttocks, the front of your waist (abdomen), or the upper arm. You should always measure your blood sugar regularly.

Penfill®
- Inject the insulin under the skin. Use the injection technique advised by your doctor or pharmacist or other health care provider and as described in your delivery system 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 and discard the needle and store Levemir® without the needle attached. Otherwise the liquid may leak out, which can cause inaccurate dosing.
- Do not refill the cartridge.
- Levemir® Penfill® cartridges are designed to be used with Novo Nordisk insulin delivery systems and NovoFine® or NovoTwist® needles.
- If you are treated with Levemir® Penfill® and another insulin Penfill® cartridge, you should use 2 insulin delivery systems, one for each type of insulin.
- As a precautionary measure, always carry a spare insulin delivery system in case your Penfill® is lost or damaged.

**If you administer more Levemir® than you should**
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.
If you administer 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 low blood sugar (a hypo) may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heartbeat; 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 low blood sugar (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.

When the symptoms of low blood sugar (hypoglycaemia) have disappeared or when your blood sugar level is stabilised, continue treatment with Levemir®.
Tell relevant people you have diabetes and what the consequences may be, including the risk of passing out (becoming unconscious) due to low blood sugar (a hypo).

Tell relevant people that if you pass out, they must turn you on your side and get medical help straight away. They must not give you any food or drink. It could choke you.
- If prolonged severe low blood sugar (hypoglycaemia) is not treated, it can cause brain damage (temporary or permanent) and even death.
- If you have low blood sugar (a hypo) that makes you pass out, or a lot of hypos, talk to your doctor. The amount or timing of insulin, food or exercise may need to be adjusted.

**If you forget to administer your Levemir®**
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 stop administering your Levemir®**
This could lead to severe hyperglycaemia (very high blood sugar) and ketoacidosis.
Do not stop taking your insulin without speaking to a doctor, who will tell you what needs to be done.
If you have any further questions on the use of this product, ask your doctor or pharmacist.

## 4. Possible side effects
Levemir® can have side effects.
**Not all side effects reported for Levemir® are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using Levemir®, please consult your doctor, pharmacist or other health care provider for advice.**
If any of the following happens, stop using Levemir® and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, tongue and mouth or throat, intestinal tract which may cause difficulty in swallowing or breathing; Symptoms of anaphylaxis reaction come on suddenly and may also include feeling unwell, start sweating and being sick (vomiting), have a rapid heartbeat and feel dizzy;
- hives, rash or itching;
- fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to Levemir®. You may need urgent medical attention or hospitalisation.
Serious allergic reaction - called a generalised allergic reaction (anaphylactic reaction or angioedema) to Levemir® or one of its ingredients. The occurrence of generalised hypersensitivity reactions is very rare but can potentially be life threatening.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
The most frequent side effect is low blood sugar (hypoglycaemia). If you administer 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.
- If you drink alcohol (see Levemir® with food, drink and alcohol).

The warning signs of low blood sugar (a hypo) may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heartbeat; feeling sick; feeling very hungry; temporary changes in vision; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; difficulty in concentrating.
These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

*Side effects occurring frequently:*

- Injection site reactions (pain, redness, hives, inflammation, bruising, swelling and itching). If they do not disappear after a few weeks, see your doctor. If you have serious or continuing reactions, you may need to stop using Levemir® and use another insulin.

*Side effects occurring less frequently:*

- Increased blood sugar (increased thirst and frequency of urination).
- Vision problems. When you start or change the dose of your treatment with Levemir®, your vision clearness may change.
- Changes at the injection site (lipodystrophy). The fatty tissue under the skin at the injection site may shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). 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, consult your doctor, pharmacist or other health care provider. These reactions can become more severe, or they may change the absorption of your Levemir®, if you inject in such a site.
- Swelling (oedema). When you start using Levemir, water retention may cause swelling around your ankles and other joints.
- Temporary worsening of diabetic retinopathy, an eye condition related to diabetes which can lead to loss of vision.
- Painful neuropathy (pain due to nerve damage).

If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please inform your doctor or pharmacist.

**Reporting of side effects**

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications: http://www.sahpra.org.za/Publications/Index/8.
By reporting side effects, you can help provide more information on the safety of Levemir®.

## 5. How to store Levemir®

Store all medicines out of reach of children.
Do not use Levemir® after the expiry date which is stated on the cartridge/FlexPen®/ label and carton after *'*Expiry*'*. The expiry date refers to the last day of that month.
Before opening: Levemir® Penfill®/FlexPen® that is not being used is to be stored in the refrigerator between 2 ˚C – 8 ˚C, away from the cooling element.
Do not freeze.
Levemir® Penfill®/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.
Penfill®: Always keep the cartridge in the outer carton when you are not using it in order to protect it from light.
FlexPen®: 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.
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.

## 6. Contents of the pack and other information

**What Levemir® contains**

Contains insulin detemir 100 U/mL (produced by recombinant DNA technology in *Saccharomyces cerevisiae*). One unit of insulin detemir contains 0,142 mg salt-free anhydrous insulin detemir. One unit (U) of insulin detemir corresponds to one IU of human insulin.

The other ingredients are disodium phosphate dihydrate;

Glycerol (E422); hydrochloric acid (for pH-adjustment) (E507); metacresol (preservative); phenol (preservative); sodium chloride, sodium hydroxide (for pH-adjustment) (E524); water for injection.; and zinc acetate (E650).

**What Levemir® looks like and contents of the pack**
Levemir® is a clear colourless liquid, free from turbidity and foreign matter.

*Levemir® Penfill®:*
Cartridges (5 x 3 mL) are made of glass, containing a bromobutyl rubber plunger and closed with a bromobutyl/polyisoprene rubber closure and sealed with a cap made of aluminium. The cartridges are packed into a carton box.

*Levemir® Flexpen® (5 x 3 mL):*
Pre-filled multi-dose disposable insulin delivery device in which a Penfill® cartridge of 3 mL made of glass, containing a bromobutyl rubber closure plunger and closed with a bromobutyl/polyisoprene rubber closure is inserted. The FlexPens are packed into a carton.

**Holder of certificate of registration**
Novo Nordisk (Pty) Ltd
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10 Marion Street Office Park
Building C1
Sandton
Johannesburg 2196

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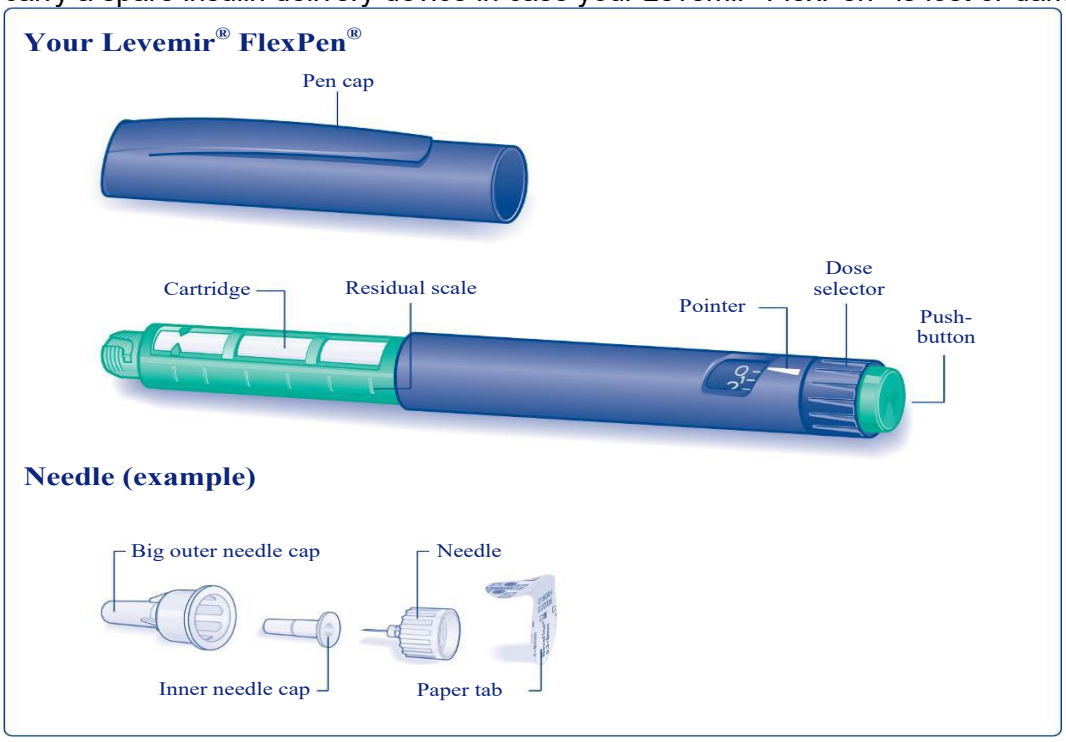
**Registration number**
34/21.1/0084

## INSTRUCTIONS FOR USE

Levemir® solution for injection in pre-filled pen, FlexPen®

**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. The Levemir® FlexPen® is designed to be used with NovoFine® or NovoTwist® disposable needles up to a length of 8 mm. As a precautionary measure, always carry a spare insulin delivery device in case your Levemir® FlexPen® is lost or damaged.




### Maintenance

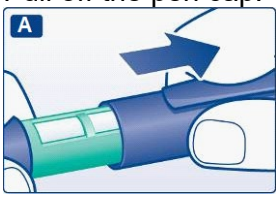
- Your Levemir® FlexPen® is designed to work accurately and safely. It must be handled with care.
- If it is dropped, damaged or crushed, there is a risk of insulin leakage.
- You can clean the exterior of your Levemir® FlexPen® by wiping it with a medicinal swab. Do not soak, wash or lubricate it as it may damage the pen.
- Do not refill your Levemir® 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.

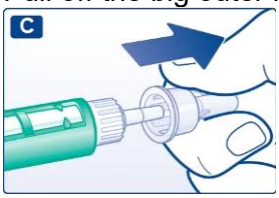



**B**

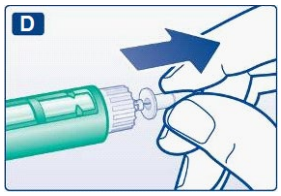
Remove the paper tab from a new disposable needle.
Screw the needle straight and tightly onto your FlexPen®.




**C**
Pull off the big outer needle cap and keep it for later.



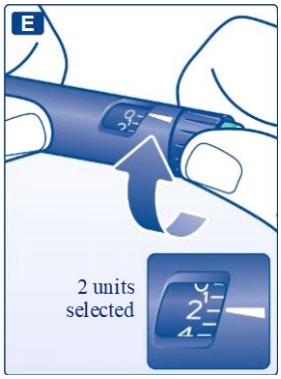

**D**
Pull off the inner needle cap and dispose of it.



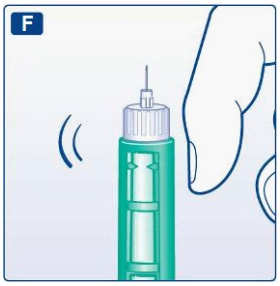

- Always use a new needle for each injection to prevent contamination.
- Be careful not to bend or damage the needle before use.
- To reduce the risk of unexpected needle sticks, never put the inner needle cap back on when you have removed it from the needle.

**Checking the insulin flow**
**Prior to each injection, small amounts of air may collect in the cartridge during normal use. To avoid injection of air and ensure proper dosing:**

**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.




**G**
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 6 times.

If a drop of insulin still does not appear, the pen is defective, and you must use a new one.

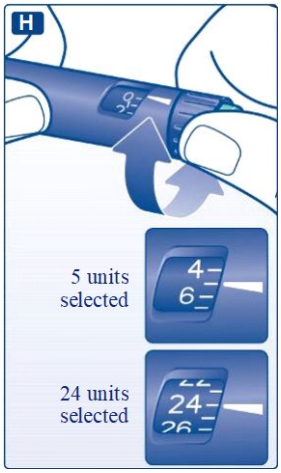



**Selecting your dose**
**Check that the dose selector is set at 0.**

**H**
Turn the dose selector to select the number of units you need to inject.

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.




- Do not use the residual scale to measure your dose of insulin.

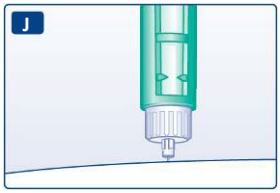
**Making the injection**
**Insert the needle into your skin. Use the injection technique shown by your doctor or nurse.**

**I**
Inject the dose by pressing the push-button all the way in until 0 lines up with the pointer. Be careful only to push the push-button when injecting.

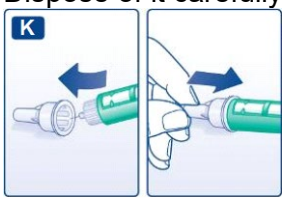
Turning the dose selector will not inject insulin.




**J**
Keep the push-button fully depressed and let the needle remain under the skin for at least 6 seconds. This will make sure you get the full dose.




**K**
Lead the needle into the big outer needle cap without touching it. When the needle is covered, carefully push the big outer needle cap completely on and then unscrew the needle. Dispose of it carefully and put the pen cap back on.




- Always remove the needle after each injection and store your Levemir® FlexPen® without the needle attached. Otherwise, the liquid may leak out which can cause inaccurate dosing.
- Caregivers should be most careful when handling used needles to avoid needle sticks.
- Dispose of the used Levemir® FlexPen® carefully without the needle attached.
- Needles and Levemir® FlexPen® must not be shared.