

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. When used in combination with a meal-related short- or rapid-acting insulin such as NovoRapid[®], Levemir treats diabetes mellitus. 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 is not recommended for you if you have type 2 diabetes *and* you take tablets to control your diabetes.

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.

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 hypoglycaemic medicines - used to treat type 2 (non-insulin dependent) 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
- fluid tablets 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
- 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.

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.

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 feel better after this, contact your doctor, diabetes education nurse, or the closest hospital.

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.

Your insulin dose may need to be changed.

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
- 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.

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.

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypos.

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)
- redness, swelling or itching at the injection site (local allergy). 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:

More severe symptoms of low blood sugar levels, including:

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

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:

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

This list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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 you are using, or that you 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 heat or direct sunlight. Protect the medicine in Levemir FlexPen from light by keeping the pen cap on when not in use.

Never use it after the expiry date printed on the label and carton.

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 yellow plastic 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: mannitol, phenol, meta-cresol, zinc acetate, sodium chloride, dibasic sodium phosphate dihydrate, sodium hydroxide, hydrochloric acid and water for injections.

Sponsor

Levemir FlexPen is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty. Ltd.

A.B.N. 40 002 879 996
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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AUST R 95211

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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

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Insulin detemir (rys)

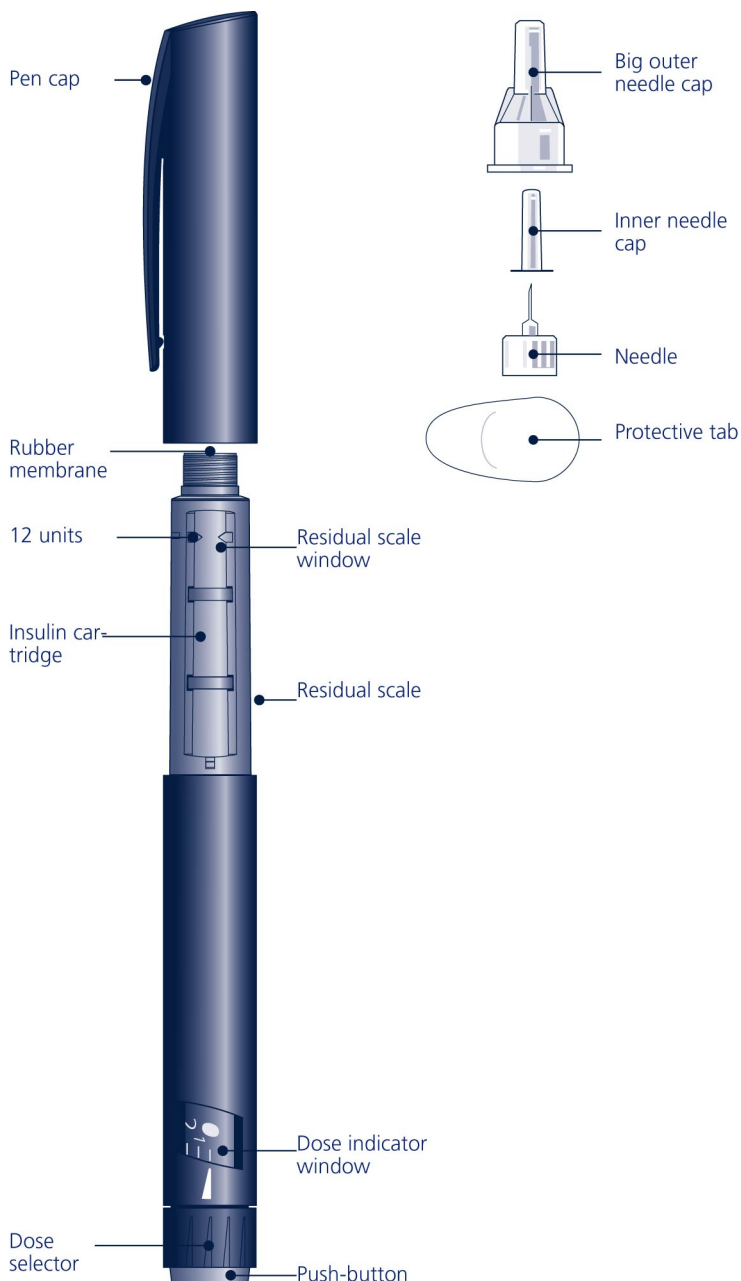
Instructions For Use

Introduction

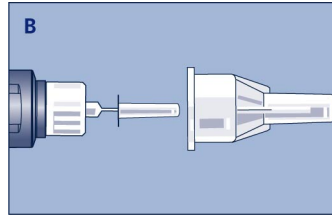
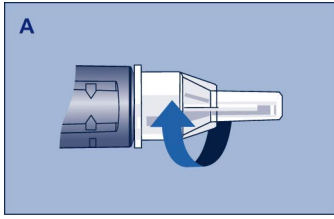
Levemir[®] FlexPen[®] is a unique, pre-filled, dial-a-dose insulin pen. You can dial doses from 1 to 60 units in increments of 1 unit. NovoFine[®] **S** needles of 8mm or shorter length are specially designed to be used with FlexPen. Look for an **S** on the needle box. The **S** stands for 'short cap'.

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

Read the following instructions carefully in order to correctly prepare your Levemir FlexPen.




Getting started

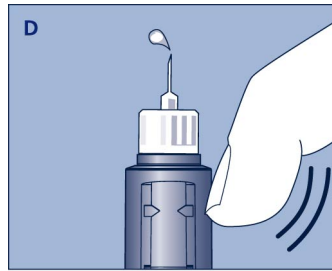
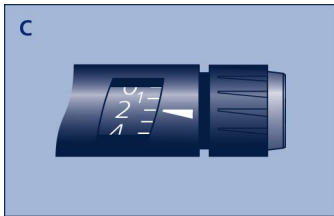


Before every injection:

Check the label to ensure that your Levemir FlexPen contains the correct type of insulin. Pull off the pen cap. Disinfect the rubber membrane with an alcohol swab prior to use.

- A. Remove the protective tab from a NovoFine  short cap needle and screw the needle onto FlexPen securely.
- B. Pull off the big outer needle cap and the inner needle cap. Do not discard the outer needle cap.

Priming FlexPen[®] prior to each injection

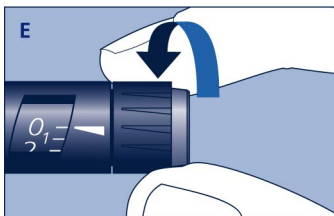


It is important to prime your FlexPen prior to every injection. The priming procedure may highlight a malfunction with FlexPen. Priming also removes any air bubbles and would help indicate whether or not a needle is blocked. If problems are encountered during priming, use an alternative insulin delivery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

- C. Dial 2 units.
- D. Hold FlexPen with the needle upwards and tap the cartridge gently with your finger a few times to make any air bubbles collect at the top of the cartridge. With the needle still pointing upwards, press the push button fully in. The dose selector should return to zero, and a drop of Levemir should appear at the needle tip – as shown in Figure D. If one does not appear, change the needle and repeat the priming procedure up to 6 times until a drop of Levemir does appear.

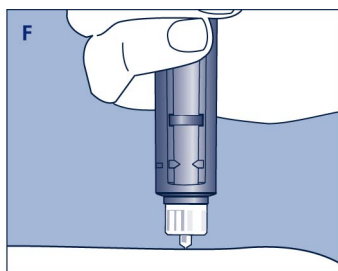
If a drop of Levemir still does not appear, FlexPen has failed to prime and must not be used.

Setting the dose



- E. Check that the dose selector is set at zero. Dial the number of units you need to inject. Do not use the residual scale to measure your dose of Levemir.
If you have set an incorrect dose, simply turn the dose selector forwards or backwards until the correct number of units has been set. When dialing backwards, be careful not to push the push button, as Levemir will be expelled. You cannot set a dose larger than the number of units left in the cartridge. **60 units is the maximum dose.**

Injecting the insulin



Use the injection technique shown to you by your doctor or diabetes education nurse. Choose a site for injection. Levemir may be injected into the abdomen, thighs, upper arms or buttocks. Change the injection site so that the same position is not used more often than once a month. This will reduce the risk of local skin reactions developing.

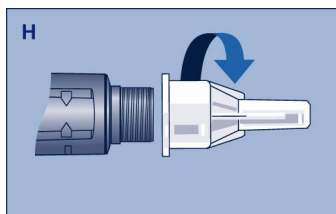
F. Pinch the skin between two fingers and push the needle into the raised skin.

G. Inject the full dose of insulin under the skin. Be careful to only push the push button when injecting – *turning the push button will not inject insulin*. Slowly count to 6 before pulling the needle out.

Keep the push button fully pushed in until you remove the needle from the skin. This will ensure that the full dose has been delivered.

If blood appears after the needle has been withdrawn, press the injection site lightly with a finger. Do not rub the area.

Removing the needle



H. Replace the big outer needle cap and unscrew the needle. Dispose of it carefully.

It is important that you use a new needle for each injection, otherwise temperature changes may cause liquid to leak out of the needle. 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 Levemir FlexPen carefully, without the needle attached.

Maintenance

FlexPen is designed to work accurately and safely. It should be handled with care. Avoid situations where FlexPen can be dropped, damaged or crushed, for there is a risk of insulin leakage.

You can clean the exterior of FlexPen by wiping it with cotton wool moistened with alcohol. Do not soak it in alcohol or wash or lubricate it as this may damage the mechanism.

Do not refill Levemir FlexPen.