

NovoMix® 30 FlexPen®

30% soluble insulin aspart (rys) and 70% insulin aspart (rys) crystallised with protamine

Consumer Medicine Information

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Instructions For Use

This leaflet answers some common questions about NovoMix® 30 FlexPen®. It does not contain all the available information. It does not take the place of talking to your doctor, diabetes education nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using NovoMix® 30 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 NovoMix® 30 is used for

The insulin aspart (rys), or “NovoMix® 30”, in NovoMix® 30 FlexPen® is a mixture of rapid- and longer-acting insulin used to treat 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.

NovoMix® 30 lowers your blood sugar level after injection. When injected under your skin, NovoMix® 30 has a faster onset of action than soluble human insulin. It takes effect within 10 to 20 minutes. The maximum effect will occur between 1-4 hours after injection and 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.

NovoMix® 30 is a pre-mixed neutral suspension consisting of rapid-acting insulin aspart (rys) (30%) and longer-acting protamine insulin aspart (rys) (70%).

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

NovoMix® 30 FlexPen® can be used alone, or together with other medicines, for treating diabetes.

NovoMix® 30 is not addictive.

NovoMix® 30 FlexPen® is available only with a doctor’s prescription.

Ask your doctor, diabetes education nurse or pharmacist if you have any questions about why NovoMix® 30 FlexPen® has been prescribed for you.

Before you use NovoMix® 30 FlexPen®

When you must not use it

Do not use the 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 a low blood sugar level (a “hypo”) when the 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 medical conditions, especially the following:

- 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 or pharmacist 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 NovoMix® 30 may interfere with each other and this may mean that your insulin dose has to change.

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

- other 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 which may also mask the symptoms of hypoglycaemia and delay recovery from hypoglycaemia
- 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
- sulfonamides – used to treat bacterial infections
- quinine – used to treat malaria and relieve muscle cramps
- quinidine – used to treat heart problems.

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

- glucocorticoids (except when applied locally) – used to treat inflammatory conditions
- oral contraceptives (“the pill”) - used for birth control
- thiazides - used to treat high blood pressure or fluid retention (oedema)
- thyroid hormones - used to treat malfunction of the thyroid gland
- sympathomimetics such as salbutamol or terbutaline - used to treat asthma

- growth hormone – used to treat growth disorders
- danazol - used to treat endometriosis, menorrhagia, fibrocystic breast disease and hereditary angioedema
- oxymetholone – used to treat certain blood disorders
- 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.

If you take the following medicines, your blood sugar level may rise or fall:

- 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.

Tell your doctor about any medicines that you are taking other than NovoMix® 30.

This is very important. Your doctor will advise you if it is all right 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 NovoMix® 30 FlexPen®

Your doctor, diabetes education nurse or pharmacist will have shown you 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 each day.

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

When to use it

NovoMix® 30 is normally used immediately (up to 10 minutes) before your meal. When necessary NovoMix® 30 may be used immediately after the meal.

How to use it

- Inject NovoMix® 30 under the skin (subcutaneous injection) as shown to you by your doctor or diabetes education nurse. **Never inject NovoMix® 30 into a vein or muscle.**
- NovoMix® 30 may be injected into the abdomen, thighs, buttocks or upper arms.
- Remember to change your injection site regularly as shown to you by your doctor or diabetes education nurse.
- Take care not to drop or knock NovoMix® 30 FlexPen®.
- Do not use NovoMix® 30 in insulin pumps.

Checking your NovoMix® 30 FlexPen®:

Check your NovoMix® 30 FlexPen® before each preparation and injection. Make sure you are using the correct type and strength of insulin.

Do not use NovoMix® 30 FlexPen® if the medicine contains clumps of material or solid white particles sticking to the bottom or wall of the cartridge after resuspending.

Read the instructions printed at the end of this leaflet carefully in order to prepare and handle your NovoMix® 30 FlexPen® correctly.

How long to use it

Do not stop using NovoMix® 30 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:

- accidentally use too much of this medicine
- have too much or unexpected exercise
- delay eating meals or snacks
- eat too little food
- 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 feel better after this, contact your doctor, diabetes education nurse, or the closest hospital.

If you do not respond to glucagon treatment, you will require medical attention.

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

If you miss a dose – Hyperglycaemia

If you forget your insulin dose, test your blood sugar level 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 – *don't forget to eat some carbohydrate within 10 minutes of your injection* – 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 NovoMix® 30 FlexPen®

Things you must do

Measure your blood sugar level regularly.

Make sure all friends, relatives, workmates or carers know that you have diabetes.

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 your doctor 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 your medicine unless your doctor tells you to.

Do not use the 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 or pens.

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 or operate a machine:

- if you have frequent hypos
- if you find it hard to recognise hypoglycaemia.

Tell your doctor if you drink alcohol.

Alcohol may mask the symptoms of hypos. If you drink 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.

Changes in diet may cause your insulin needs to change.

Side effects

Tell your doctor, diabetes education nurse or pharmacist as soon as possible if you do not feel well while you are using NovoMix® 30 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, hives, bruising, swelling 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 NovoMix® 30 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 NovoMix® 30 FlexPen®

Storage

Store NovoMix® 30 FlexPen® that are not being used between 2°C and 8°C in a refrigerator (away from the cooling element).

Resuspend the insulin in your NovoMix® 30 FlexPen® – whether it is to be used immediately or whether it is to be carried as a spare – upon removing it from the refrigerator.

Do not keep the NovoMix® 30 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 NovoMix® 30 FlexPen® after 4 weeks even if there is still some medicine left in it.

The medicine in your NovoMix® 30 FlexPen® must not be frozen, or exposed to excessive heat or light. Protect the medicine in NovoMix® 30 FlexPen® from light by keeping the cap on when not in use.

Never use NovoMix® 30 FlexPen® after the expiry date printed on the label and carton.

Never use NovoMix® 30 FlexPen® if NovoMix® 30 does not appear white and uniformly cloudy after resuspension.

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

NovoMix® 30 is a white, cloudy suspension for subcutaneous injection. NovoMix® 30 FlexPen® is a 3mL pre-filled glass cartridge contained in a dial-a-dose insulin pen.

Ingredients

NovoMix® 30 contains soluble insulin aspart (rys) and protamine-crystallised insulin aspart (rys) 100 units per mL (100 U/mL) as the active ingredient, in the ratio of 30:70.

The abbreviation “rys” indicates the method of genetic engineering used to manufacture the insulin aspart.

NovoMix® 30 FlexPen® also contains the following inactive ingredients: glycerol, phenol,

metacresol, zinc chloride, sodium chloride, dibasic sodium phosphate dihydrate, protamine sulfate (a fish product), sodium hydroxide, hydrochloric acid and water for injections.

Sponsor

NovoMix® 30 FlexPen® is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty. Ltd.

Level 3
21 Solent Circuit
Baulkham Hills NSW 2153

NovoMix® 30 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

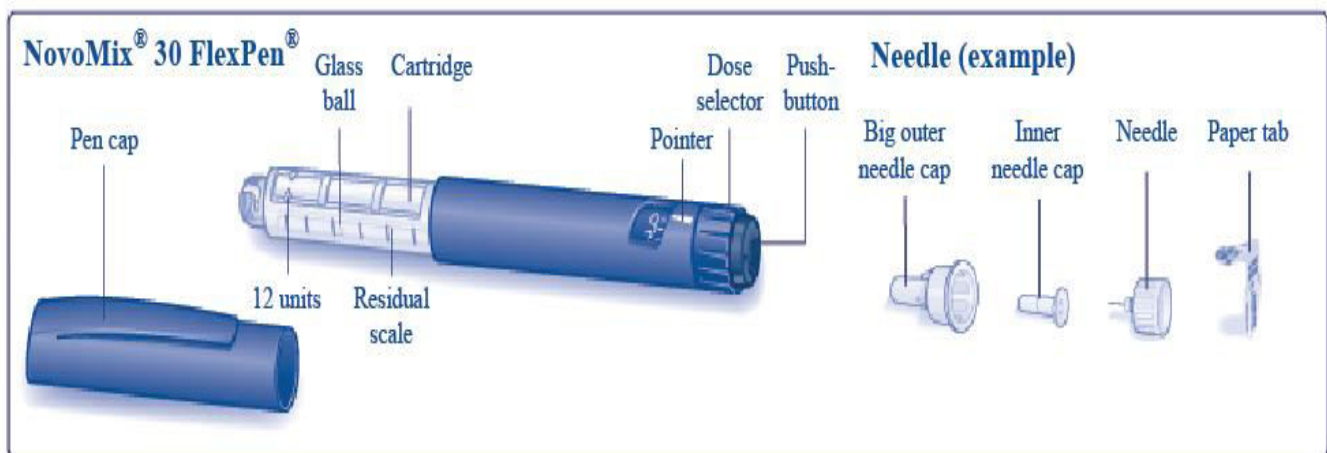
Instructions For Use

Instructions

Please read the following instructions carefully before using your NovoMix® 30 FlexPen®. 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 levels.

Your FlexPen® is a prefilled, 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® 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.



Caring for your pen

Your FlexPen® must be handled with care. If it is dropped, damaged or crushed, there is a risk of insulin leakage. This may cause inaccurate dosing, which can lead to too high or too low blood sugar levels.

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

Do not refill your FlexPen®.

Preparing your NovoMix® 30 FlexPen®

A

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

Every time you use a new pen

Let the insulin reach room temperature before you use it.

This makes it easier to resuspend.

Pull off the pen cap (see A).



B

Before your first injection with a new FlexPen®, you must resuspend the insulin:

Roll the pen between your palms 10 times – it is important that the pen is kept horizontal.



C

Then move the pen up and down 10 times between the two positions as shown, so the glass ball moves from one end of the cartridge to the other.



Repeat rolling and moving the pen until the liquid appears uniformly white and cloudy (resuspended).

For every subsequent injection:

Move the pen up and down between the two positions - as shown in Figure C - at least 10 times until the liquid appears uniformly white and cloudy. If the resuspension procedure alone is not enough to give a uniformly white and cloudy liquid, repeat the rolling and moving procedures (see B and C) until the liquid does appear uniformly white and cloudy.

Always make sure that you have resuspended the insulin prior to each injection. This reduces the risk of too high or too low blood sugar levels occurring. After you have resuspended the insulin, complete all the following steps of injection without delay.

- Always check there are at least 12 units of insulin left in the cartridge to allow resuspension. If there are fewer than 12 units left, use a new FlexPen®.

Attaching a needle

D

Remove the paper tab from a new disposable needle.



Screw the needle straight and tightly onto your FlexPen®.

E

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



F

Pull off the inner needle cap and dispose of it. Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.



- Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.
- Be careful not to bend or damage the needle before use.

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:

G

Turn the dose selector to select 2 units.



H
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.



I
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.



- 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 selector 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 levels.

Selecting your dose

Check that the dose selector is set at 0.

J
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.



- Always use the dose selector and the 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 residual scale, it only shows approximately how much insulin is left in your pen.

Making the injection

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

K
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.



L

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. Withdraw the needle from the skin, then release the pressure on the push-button.

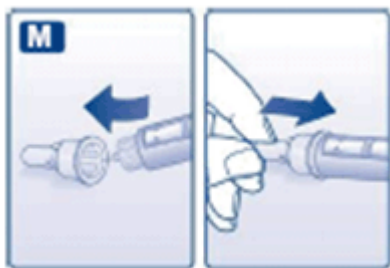
Always make sure that the dose selector returns to 0 after the injection. If the dose selector stops before it returns to 0, the full dose has not been delivered, which may result in too high blood sugar levels.



M

Guide the needle into the big outer needle cap without touching it, as shown. 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 FlexPen® without the needle attached. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

Further important information

- Caregivers must be very careful when handling used needles to reduce the risk of needle sticks and cross-infection.
- Dispose of your used FlexPen® carefully without the needle attached.

- Never share your FlexPen® or 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.
- Always keep your pen and needles out of sight and reach of others, especially children.