GENSULIN M30 (30/70)100IU/ml Suspension for Injection

Human Insulin (30% regular, 70% isophane)

What is in This Leaflet:

What Gensulin M30 (30/70) is used for

Gensulin M30 (30/70) contains the active substance human insulin, which is used to treat diabetes. Diabetes mellitus is condition in which a person has high blood sugar, either because the pancreas does not produce enough insulin or the cells do not respond to the insulin that is produced; therefore, extra insulin is needed to lower your blood sugar levels. Gensulin M30 (30/70) is a premixed suspension of an intermediate-acting and fast-acting insulin.

How Gensulin M30 (30/70) works

After administration of Gensulin M30 (30/70) , it will start to lower your blood sugar in about half an hour, and the effect will last for approximately 24 hours.

Before you use Gensulin M30 (30/70)

When you must not use it

- If you are allergic (hypersensitive) to any of the ingredients in Gensulin M30 (30/70) (see section list of ingredients). Watch out for the signs of allergy in section *Possible side effects* or ask your doctor for clarification.
- If you experience symptoms of low blood sugar levels (hypoglycaemia), or a hypoglycaemic attack (symptom of low blood sugar). See section *What to do in an emergency* to know more about hypoglycaemia.

Before you start to use it

Inform your doctor if:

- You have any other medical conditions, such as infection, fever, kidney or liver problems. Some medical conditions can alter your insulin requirements and your doctor will suggest a change in dose.
- You are pregnant, planning a pregnancy or breast-feeding. The amount of insulin you need usually falls during the first three months of pregnancy and increases for the remaining six months. If you are breast-feeding, you may need to alter your insulin intake or diet.

Site of injection

Gensulin M30 (30/70) is for injection under the skin (subcutaneously). Never inject your insulin directly into a vein or muscle.

Skin changes at the injection site:

The injection site should be rotated to prevent skin changes such as lumps under the skin. The insulin may not work very well if you inject into a lumpy area. Contact your doctor if you are currently injecting into a lumpy area 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 medications dose (see *Possible side effects*).

Taking other medicines

Many medicines affect the way glucose works in your body and they may influence your insulin dose.

Talk to your doctor or pharmacist if you take or have recently taken any other medicines, even those not prescribed.

Listed below are the most common medicines which may affect your insulin treatment.

monoamine oxidase inhibitors (MAOI); beta-blockers; ACE-inhibitors; acetylsalicylic acid; anabolic steroids; sulphonamides; oral contraceptives; thiazides; glucocorticoids; thyroid hormone therapy; beta-sympathomimetic; growth hormones; danazol; octreotide or lanreotide.

Pioglitazone (oral antidiabetic medicine 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 were treated with pioglitazone and insulin experienced the development of 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 localise swelling (oedema).

How to use Gensulin M30 (30/70)

General instructions

Follow your doctor's advice about how to use, when to use and how long to use.

This leaflet is only a general guide. If your doctor has switched you from other type or brand of insulin, or if you are suffering from a medical condition, your dose may have to be adjusted by your doctor.

The best places to give yourself an injection are: the front of your waist (abdomen); your buttocks; the front of your thighs or upper arms. Your insulin will work more quickly if you inject it around the waist.

How to use Cartridge

Things to be checked before using

- Check the label to make sure it is the right type of insulin.
- Always check the cartridge, including the rubber plunger (stopper).
- Don't use it if any damage is seen.
- Take it back to your supplier. See your insulin delivery device manual for further instructions.
- Disinfect the rubber membrane with a medicinal swab.
- Always use a new needle for each injection to prevent contamination.

Do not use

- In insulin infusion pumps.
- If the compatible insulin injector pen is dropped, damaged or crushed, there is a risk of leakage of insulin.
- If it hasn't been stored correctly or been frozen.
- If it's not uniformly white and cloudy when it's re-suspended.

How much to use

Dosage

- Your doctor has told you which

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insulin to use, how much, when and how often to inject. These instructions are only for you. Follow them exactly and visit your diabetes clinic regularly.

- If you change your insulin type (for example from animal to human), you may have to take more or less than before. This might just be for the first injection or it may be a gradual change over several weeks or months.
- Inject Gensulin M30 (30/70) under the skin. You should not administer it using a different administration route. Under no circumstances should Gensulin M30 (30/70) be given into a vein.

Instruction for use

- Inject the insulin under the skin.
- Use the injection technique advised by your doctor or diabetes nurse and described in your insulin delivery device manual.
- Keep the needle under your skin for at least 10 seconds to make sure that the full dose has been delivered.
- After each injection be sure to remove and discard the needle and store Gensulin M30 (30/70) without the needle attached. Otherwise, the liquid may leak out which can cause inaccurate dosing.
- Do not mix any other insulin in an Gensulin M30 (30/70) cartridge. Once the cartridge is empty, do not use it again.

Direction of Use of reusable pen with Cartridges.

- For use with re-usable pen injector only. Please refer to the instruction of use of the pen injector for more information.

When to use it

Use as directed by doctor or pharmacist.

How long to use it

Continue taking Gensulin M30 (30/70) for as long as your doctor recommends.

If you forget to use it

If you take less Gensulin M30 (30/70) than you need or if you forget to take a dose your blood sugar levels may increase. Check your blood sugar.

If you use too much (overdose)

If you take more Gensulin M30 (30/70) than your requirement it may cause hypoglycaemia(low blood sugar).

If you stop using it

If you stop taking Gensulin M30 (30/70) than you need, your blood sugar levels may become too high.

Do not change your insulin unless your doctor tells you to.

If you have any further questions on the use of this product, ask your diabetes specialist nurse, doctor or pharmacist.

While you are using it

Things you must do

- Eat a meal or snack containing carbohydrates within 30 minutes of the injection.
- It is recommended that you measure your blood glucose regularly and have regular check-ups.

Things you must not do

*Driving and using machines***:** your ability to concentrate and react may be reduced if you have hypoglycaemia (low blood sugar). You should contact your doctor about the advisability of driving, if you have:

- Frequent episodes of hypoglycaemia.
- Reduced or absent warning signs of hypoglycaemia.

Things you must be careful of

- *If you have a habit of drinking*: watch for signs of hypoglycaemia and never drink alcohol on an empty stomach. The amount of insulin you need may also change if you drink alcohol.
- If you have trouble with your kidneys or liver, or with your adrenal, pituitary or thyroid glands
- If you are exercising more than usual or if you want to change your usual diet.
- *If you are going abroad:* travelling over time zones may affect your insulin needs and the timing of your injections.
- If you had hypoglycaemia (low blood sugar) after switching from animal insulin to human insulin and reported that the early warning symptoms were less obvious or different.
- If you are ill: carry on taking your insulin
- If you often have hypoglycaemia or have difficulty recognising the symptoms, please discuss this with your doctor.

Side effects

The most common side effect is hypoglycaemia.

You get a hypoglycaemic attack if your blood sugar gets too low. This might happen:

- If you take too much insulin.
- If you eat too little or miss a meal.
- If you exercise more than usual.
- If you have an infection or illness (especially diarrhoea or vomiting);
- If you have a change in your need for insulin; or
- If you have trouble with your kidneys or liver which gets worse.

If you take less Gensulin M30 (30/70) than your requirement it may cause hyperglycaemia (high blood sugar).

Common side effects

Symptoms resulting from release of adrenaline are common manifestations of mild to moderate hypoglycaemia. They include cold sweats, anxiety, shakiness, hunger, rapid heartbeat, headache, and nervousness. Weight gain is common when taking insulin.

Less common side effects

Allergic reactions and changes at the injection site (lipodystrophy) may occur at the injection site as a consequence of failure to rotate injection sites within an area. If you inject yourself too often at the same site, fatty tissue under the skin at this site may shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by build-up of a protein called amyloid. Changes at the injection site (Cutaneous amyloidosis); how often this occurs is not known. Changing the site with each injection may help to prevent such skin changes. If you noticeyour skin pitting or thickening at theinjection site, tell your doctor because these reactions can become more severe, or they may change the absorption of your insulin if you inject in such a site.

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Signs of allergy
Reactions (redness, swelling, itching) at the injection site may occur (local allergic reactions). These usually disappear after a few weeks of taking your insulin. If they do not disappear, see your doctor.

Seek medical advice immediately
- If signs of allergy spread to other parts of the body, or
- If you suddenly feel unwell and you start sweating; start being sick (vomiting); have difficulty in breathing; have a rapid heartbeat; feel dizzy; feel like fainting.

You may have a very rare serious allergic reaction to Gensulin M30 (30/70) or one of its ingredients (called a systemic allergic reaction). See also warning section *Before you use Gensulin M30 (30/70)*

Abnormal accumulation of fluid (oedema)*:* It may occur upon initiation of insulin therapy. These symptoms are usually of transitory nature.

Vision problems*:* you might experience transient visual disturbances when you initiate treatment with insulin.

Painful neuropathy (nerve related pain)*:* If your blood glucose levels improve very fast it may cause a burning, tingling or electric pain. This is called acute painful neuropathy and it usually disappears. If it does not disappear, see your doctor.

Diabetic retinopathy (eye background changes): If you have diabetic retinopathy and your blood glucose levels improve very fast, the retinopathy may get worse. Ask your doctor about this. If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider (doctor, nurse, or pharmacist)

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03- 78835490, or visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

What to do in an emergency

If you get a hypoglycaemic attack
Hypoglycaemia means your blood sugar level is too low.

Causes of hypoglacaemic attack
• If you take too much insulin.
• If you eat too little or miss a meal.
• If you exercise more than usual.
• If you have an infection or illness (especially diarrhoea or vomiting);
• If you have a change in your need for insulin; or
• If you have trouble with your kidneys or liver which gets worse.

The warning signs of a hypoglycaemic attack 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 get any of these signs:
- Eat glucose tablets or a high sugar snack (sweets, biscuits, fruit juice), then rest.
- Don't take any insulin if you feel a hypoglycaemic attack coming on.
- Carry glucose tablets, sweets, biscuits or fruit juice with you, just in case.
- Tell your relatives, friends and close colleagues that if you pass out (become unconscious), they must: turn you on your side and seek medical advice straight away. They must not give you any food or drink as it could choke you.
- If severe hypoglycaemia is not treated, it can cause brain damage (temporary or permanent) and even death.
- If you have a hypoglycaemic attack that makes you pass out, or a lot of hypoglycaemic attack, talk to your doctor. The amount or timing of insulin, food or exercise may need to be adjusted.

Using glucagon
You may recover more quickly from unconsciousness with an injection of the hormone glucagon by someone who knows how to use it. If you are given glucagon you will need glucose or a sugary snack as soon as you are conscious. If you do not respond to glucagon treatment, you will have to be treated in a hospital. Seek medical advice after an injection of glucagon; you need to find the reason for your hypoglycaemic attack to avoid getting more.

If you get a hyperglycaemia
If your blood sugar gets too high. Your blood sugar may get too high (this is called hyperglycaemia).

Causes of hyperglycaemia
- Having forgotten to take your insulin.
- Repeatedly taking less insulin than you need.
- An infection or a fever.
- Eating more than usual.
- Less exercise 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.

If you get any of these signs:
Test your blood sugar level and test your urine for ketones if you can. Then seek medical advice straight away.
These may be signs of a very serious condition called diabetic ketoacidosis. If you don't treat it, this could lead to diabetic coma and death.

Storage and Disposal of Gensulin M30 (30/70)

How to store
a. Do not store Gensulin M30 (30/70) cartridge in or too near the freezer or cooling element.
b. Keep the Gensulin M30 (30/70) cartridge in the outer carton in order to protect from light.
c. Protect from excessive heat and direct sunlight
d. Store in a refrigerator at temperature between 2°C and 8°C.
e. Do not freeze. Gensulin M30 (30/70) cartridge which are in use can be kept at room temperature (upto 30°C) for up to 42 days.
f. Gensulin M30 (30/70) which have been

frozen must not be used.

g. Keep Gensulin M30 (30/70) out of reach of children.

How to Dispose

Any unused product or waste material should be disposed of in accordance with local requirements. Gensulin should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required.

Product Description

What it looks like

The suspension for injection comes as cloudy, white, aqueous suspension.

Gensulin M30 (30/70) *Cartridge*

It is supplied in 3 mL colourless glass cartridges (Type 1) sealed using lined seals, plugged with plunger stoppers and glass bead.

Ingredients

Active Ingredients

1 mL contains100 IU of insulin human.

Inactive Ingredients

The other ingredients are Metacresol, Phenol, Glycerol, Protamine sulphate, Zinc oxide, Hydrochloric acid, Sodium hydroxide, Disodium hydrogen phosphate dodecahydrate and Water for Injections.

MAL Number

MAL25016008AZ

Manufacturer :

Bioton S.A.
Macierzysz, ul. Poznańska 12
05-850 Ożarów Mazowiecki
Poland.

Product Registration Holder:

Pharmaniaga Marketing Sdn Bhd
No. 7, Lorong Keluli 1B, Kawasan
Perindustrian Bukit Raja Selatan,
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Malaysia

Date of Revision:

23/06/2025

Serial number:

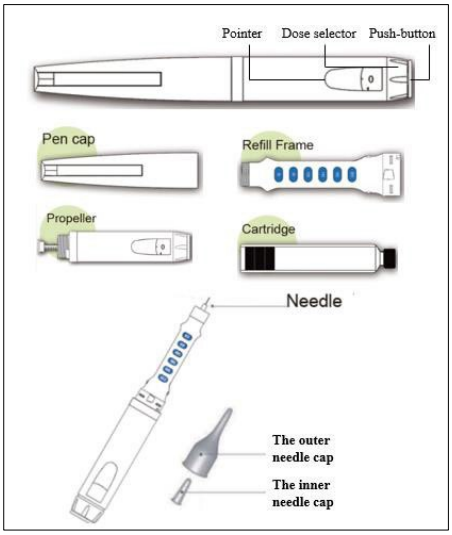
NPRA (R3)25/82

INSTRUCTIONS ON HOW TO USE PEN INJECTOR

Read the following instructions carefully before using your Pen Injector. 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 level.

Gensulin can be used with the DELFU pen injector and the PENOVVA pen injector

Your Pen Injector is designed to be used, with disposable needles. The pen is suitable for BD needle and NOVO. As a precautionary measure, always carry a spare insulin delivery device in case your Pen Injector is lost or damaged.



Caring your Pen Injector

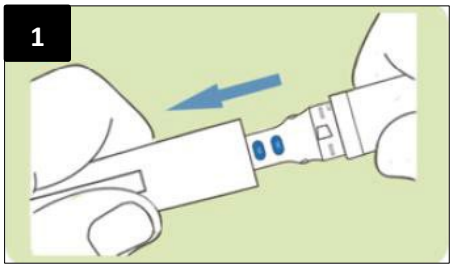
Your Pen Injector must be handled with care.

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 level.

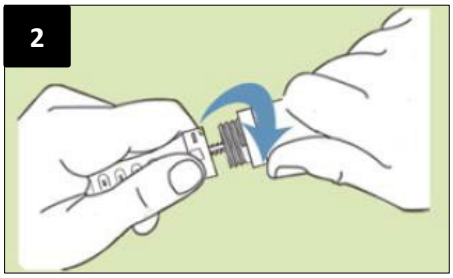
You can clean the exterior of your Pen Injector by wiping it with a medicinal swab. Do not soak it, wash or lubricate it as it may damage the pen.

Preparing Pen Injector

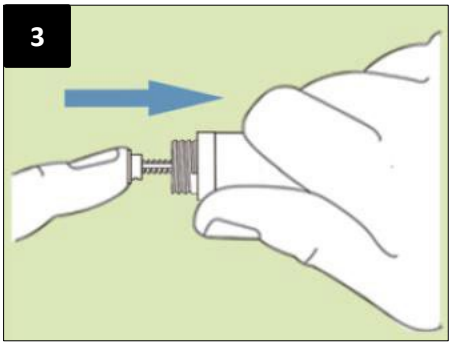
Check the name of insulin cartridge to make sure that it contains the correct type of insulin. This is especially important if you take more than one type of insulin. If you take more than one type of insulin, your blood sugar level may get too high or too low.



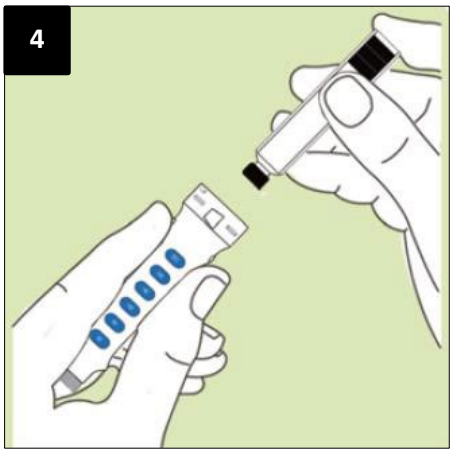
Get the pen from the box, unplug the cap.



Unscrew the cartridge holder.

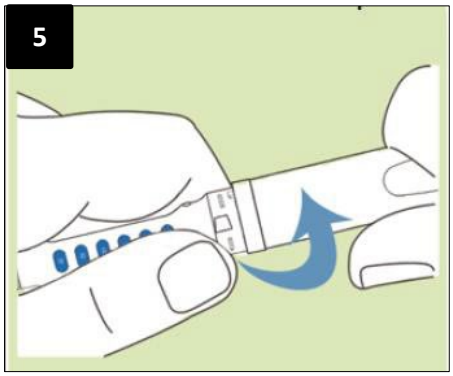


Push back the screw until the internal plunger fully retracted.



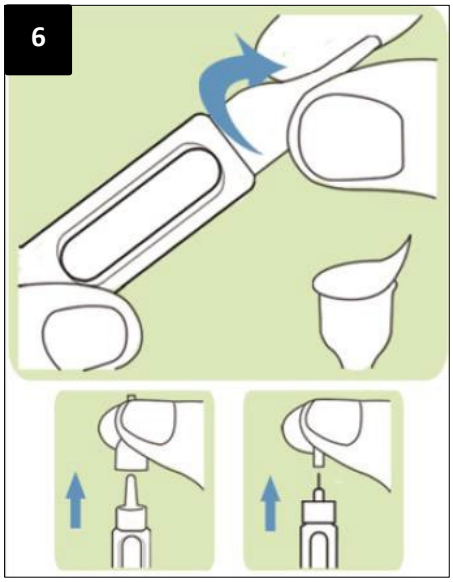
Insert the cartridge into the Refill Frame, putting the small end of the cartridge into the cartridge holder.

Note: Please make sure the cartridge is not broken before you install the cartridge.



Screw the cartridge holder back onto the pen body until it is secure.

Note: If the cartridge is not installed properly, you may be unable to screw on the cartridge holder and may not be able to inject the correct dose.



Remove the protective sheet, then screw the needle onto the cartridge holder, remove the needle cap and make sure the needle is not bent or damaged.

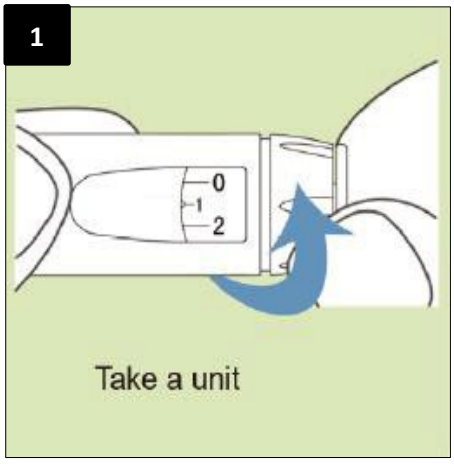
Note: Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

Be careful not to bend or damage the needle before use.

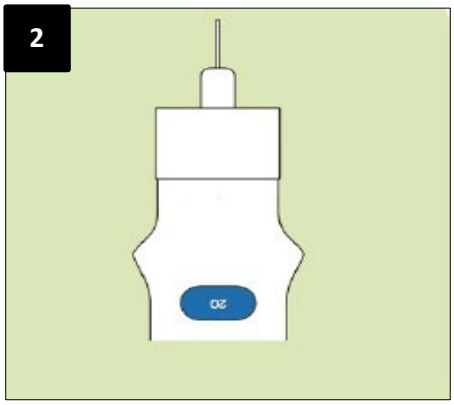
Checking the insulin flow.

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:

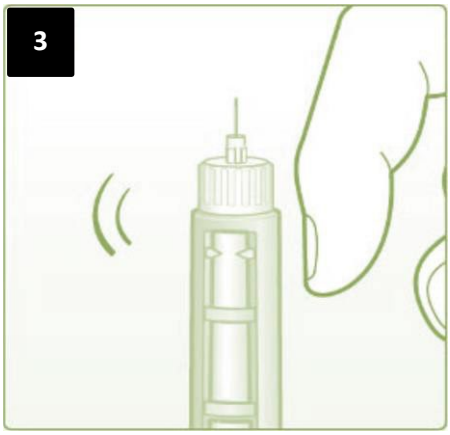
Before each injection it is required to install a new needle.



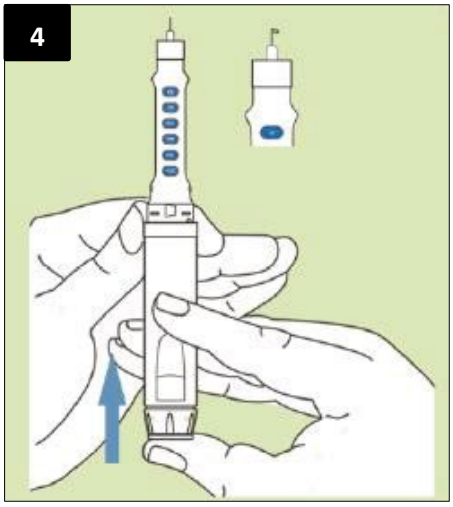
Turn the dose selector, select a dose that you want to inject.



Put the pen vertical and the pen needle upward.

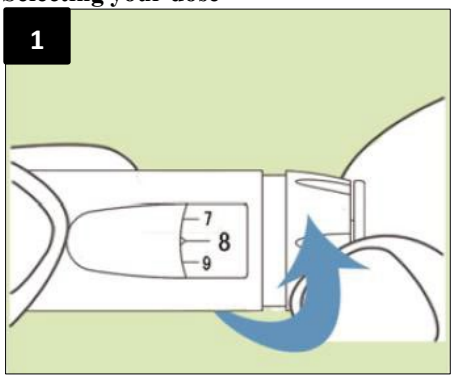


Hold your Pen Injector with the needle pointing upwards and tap the cartridge gently with your finger a few times to make any air bubbles collect at the top of the cartridge.

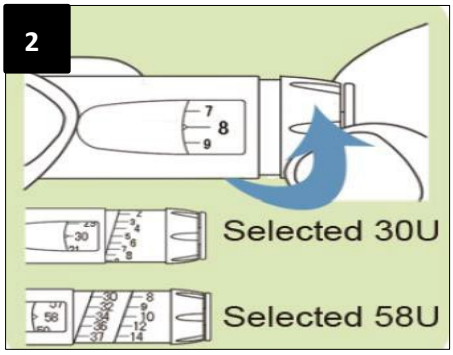


Press the injection button till you see liquid hanging on the tip. If not, change the needle and repeat the procedure. If a drop of insulin still does not appear, the pen is defective, and you must use a new one.

Selecting your dose



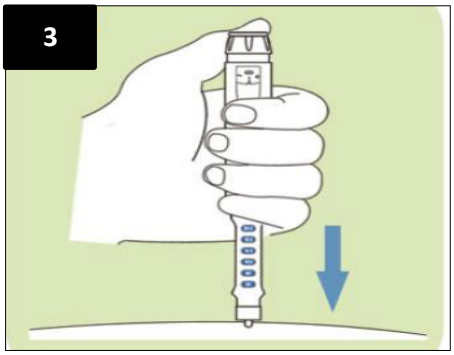
Turn the dose selector to select the number of units you need to inject.



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. The maximum dose is 0.6ml, if you dose is large than 0.6ml, you should be injected twice.

Always use the dose selector and the pointer to see how many units you have selected before injecting the insulin.

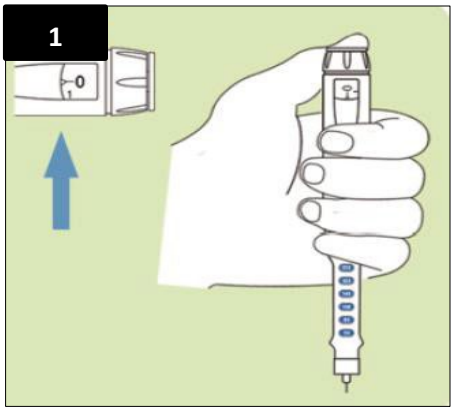


At the end of an injection, the number in the window should be "0", if it is not, this is amount of insulin you did not receive, remember this number, remove the needle and the empty cartridge.

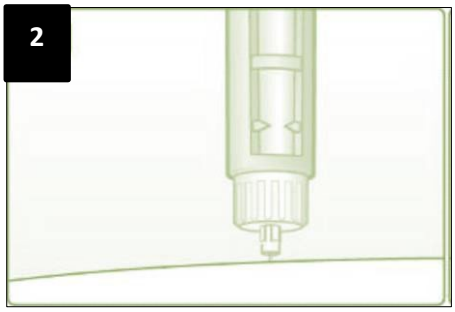
If you select and inject the wrong dose, your blood sugar level may get too high or too low. Do not use the residual scale, it only shows approximately how much insulin is left in your pen.

Making the injection

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



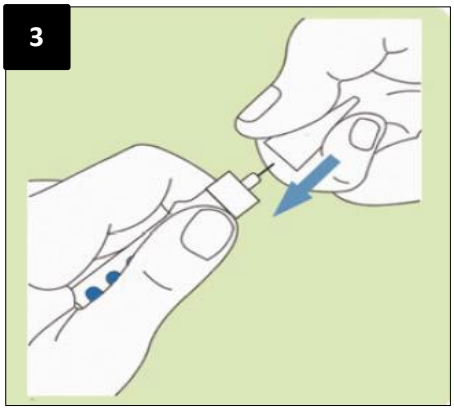
Inject the dose by pressing the push-button all the way in until 0 lines up with the pointer. Be careful only to push the push-button when injecting.



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 level.



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 Pen Injector 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 Pen Injector carefully without the needle attached.

Never share your pen or your 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.