

Wosulin™-N, Human Insulin (NPH Human Insulin Isophane (100 IU/ml)

Wosulin™-R, Regular Human Insulin Soluble (100 IU/ml)

Wosulin™-30/70, Mixed Human Insulin (30% regular, 70% isophane)

What is in this leaflet

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What Wosulin™ products is used for

Wosulin™ products contains the active human insulin and is used to treat diabetes.

Your doctor may tell you to use **Wosulin™-N as a longer-acting insulin** and **Wosulin™-R as a fast-acting insulin**. Do not change your insulin unless your doctor tells you to. Be very careful if you do change insulin. Each type of insulin has a different **colour on the pack** and the cartridge so that you can easily tell the difference.

How Wosulin™ products works

Wosulin™ products contains the active substance human insulin, which is used to treat diabetes. You get diabetes if your pancreas does not make enough insulin to control the level of glucose in your blood (blood sugar). Wosulin™ products is used to control glucose in the long term.

Wosulin™-N, its action is prolonged by the inclusion of protamine sulphate in the suspension.

Wosulin™-R is a rapidly acting insulin preparation.

Wosulin™-30/70, It is a premixed suspension of rapid and long acting insulin. Its action is prolonged by the inclusion of protamine sulphate in the suspension.

Before you use Wosulin™ products

- When you must not use it

Do not take this medicine if:

- you are allergic to human insulin or any other ingredients of this medicine (listed in Product Description)

- Before you start to use it

Do not use Wosulin™ products if you think hypoglycaemia (low blood sugar) is starting. Further in this leaflet it tells you how to deal with mild hypoglycaemia.

Pregnancy and lactation

Please consult your doctor or pharmacist if you are pregnant, planning for pregnancy or breast-feeding before using any medicine. 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.

Take special care with Wosulin™ products

- If your blood sugar levels are well controlled by your current insulin therapy, you may not feel the warning symptoms when your blood sugar is falling too low. You must think carefully about when to have your meals, how often to exercise and how much to do. You must also keep a close watch on your blood sugar levels by testing your blood glucose often.
- A few people who have had hypoglycaemia (low blood sugar) after switching from animal insulin to human insulin have reported that the early warning symptoms were less obvious or different. If you often have hypoglycaemia or have difficulty recognising the symptoms, please discuss this with your doctor.
- If you answer YES to any of the following questions, tell your diabetes specialist nurse, doctor or pharmacist.
 - Have you recently become ill?

- Do you have trouble with your kidneys or liver?

- Are you exercising more than usual?

- The amount of insulin you need may also change if you drink alcohol.
- You should also tell your diabetes specialist nurse, doctor or pharmacist if you are planning to go abroad. The time difference between countries may mean that you have to have your injections and meals at different times to when you are at home.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Your insulin needs may change if you are taking any of the following:

- steroids,
- thyroid hormone replacement therapy,
- oral hypoglycaemics (antidiabetic medication),
- acetylsalicylic acid (aspirin),
- some antidepressants (monoamine oxidase inhibitors),
- some angiotensin converting (ACE) inhibitors (for example captopril, enalapril) or angiotensin II receptor blockers.

How to use Wosulin™ products

- How much to use

Always check the pack and the cartridge label for the name and type of the insulin when you get it from your pharmacy. Make sure you get the Wosulin™ products that your doctor has told you to use.

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help.

Dosage

- You should normally inject Wosulin™-N as your basal insulin.

- Your doctor has told you which 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 Wosulin™ products under the skin. You should not administer it using a different administration route.
- Wosulin™-N and Wosulin™-30/70, under no circumstances should be given into a vein.

Preparing Wosulin™ products

- Wosulin™-R is already dissolved in water, so you do not need to mix it. But you must use it only if it looks like water. It must be clear, have no colour and no solid particles in it. Check each time before you inject yourself.
- Wosulin™-N and Wosulin™-30/70 should be rotated several times in the palms of the hands before use to resuspend insulin until it appears uniformly cloudy or milky. If not, repeat the above procedure until contents are mixed.
- Do not shake vigorously as this may cause frothing which may interfere with the correct measurement of the dose. The cartridge should be examined frequently and should not be used if clumps of material are present or if solid white particles stick to the bottom or sides of the cartridge, giving it a frosted appearance. Check each time before you inject yourself.

Getting the pen ready to use

First wash your hands.

Read the instructions on how to use your Pen Injector. Please follow the instructions carefully. Here are some reminders.

- Use a clean needle.

- Prime your Wosulin™ products before each use. This checks that insulin comes out and clears the air bubbles from your Wosulin™ products. There may still be some small air bubbles left in the pen – these are harmless. But if the air bubbles are too large it may affect the insulin dose.

Injecting Wosulin™ products

- First wash your hands.
- Before you make an injection, clean your skin as you have been instructed.
- Clean the rubber stopper on the cartridge, but do not remove the stopper.
- Administration (injection method) as per pen & cartridge rather than vial with syringe & needle. Your doctor will tell you how to do this.

Do not share your needles or your pen.

- Inject under the skin, as you were taught. Do not inject directly into a vein.
- After your injection, pull the needle out and apply gentle pressure over the injection site for several seconds to make sure you have taken the whole dose. Do not rub the area you have just injected. Make sure you inject at least half an inch (1 cm) from where you last injected and that you ‘rotate’ the places you inject, as you have been taught.
- You should never mix **Wosulin™-R** and **Wosulin™-N** with insulins produced by other manufacturers or animal insulins.
- You must not inject Wosulin™ products into a vein. Inject Wosulin™ products as your diabetes specialist nurse or doctor has taught you.
- Only your doctor can inject Wosulin™-R into a vein. He or she will only do this under special circumstances such as surgery or if

you are ill and your glucose levels are too high.

After injecting

As soon as you have done the injection, cap the needle and carefully unscrew the needle from the pen. This will keep the insulin sterile, prevents leaks, stops air from entering the pen and prevents the needle from getting clogged. Do not share your needles or pen with anyone. Afterward, put the cap back on your pen.

Further injections.

Every time you use a pen you must use a new needle. Before every injection, clear any air bubbles. You can see how much insulin is left by holding the Wosulin™ products with the needle pointing up. The scale on the cartridge shows about how many units you have left.

Do not mix any other insulin in your disposable pen. Once the Wosulin™ products is empty, do not use it again. Please get rid of it carefully - your pharmacist or diabetes nurse will tell you how to do this.

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Use Wosulin™ products for the duration that the doctor recommends.

- If you forget to use it

if you take less Wosulin™ products than you need, your blood sugar levels may increase. Check your blood sugar.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you or anyone else may have used too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

If you take more Wosulin™ products than you need, your blood sugar may become low. Check your blood sugar.

While you are using it**- Things you must do**

Use your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are using **Wosulin™** products.

Tell your doctor immediately if you become pregnant while using this medication.

Take **Wosulin™** products only with a doctor's prescription.

If you experience hypoglycaemia (low blood sugar), eat glucose tablets, sugar or drink a sugary drink. Then eat fruit, biscuits, or a sandwich, as your doctor has advised you and have some rest. This will often get you over mild hypoglycaemia or a minor insulin overdose. If you get worse and your breathing is shallow and your skin gets pale, tell your doctor at once.

- Things you must not do

Do not stop using the medicine unless advised by your doctor.

Do not use any new medicines without consulting your doctor or pharmacist.

Do not give **Wosulin™** products to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of**Driving and using machines**

Your ability to concentrate and react may be reduced if you have hypoglycaemia (low blood sugar). Please remember this in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). You should contact your diabetes specialist nurse or doctor about the advisability of driving if you have:

- frequent episodes of hypoglycaemia.
- reduced or absent warning signs of hypoglycaemia.

Side effects

Like all medicines, **Wosulin™** products can cause side effects, although not everybody gets them.

Human insulin may cause hypoglycaemia (low blood sugar). The first symptoms of hypoglycemia come early and include the following:

- tiredness
- nervousness or shakiness
- headache
- rapid heartbeat
- feeling sick
- cold sweat

Systemic allergy. The symptoms are as follows:

- fall in blood pressure
- difficulty in breathing
- fast heart beat
- rash over the whole body
- wheezing
- sweating

If you think you are having this sort of insulin allergy with **Wosulin™** product, tell your doctor at once.

Local allergy. Some people get redness, swelling or itching around the area of the insulin injection. This usually clears up in anything from a few days to a few weeks. If this happens to you, tell your doctor.

Lipodystrophy (thickening or pitting of the skin). If you notice your skin thickening or pitting at the injection site, change your injection site and tell your doctor.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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

Storage and Disposal of **Wosulin™ product****- Storage**

Keep out of the reach and sight of children.

Before the first use store your **Wosulin™** products in a refrigerator (2°C – 8°C). **Do not freeze.** You can keep your 'in use' cartridge at room temperature (below 30°C) for up to 28 days. Do not put it near heat or in the sun.

Do not use **Wosulin™** products after the expiry date which is stated on the label and the carton. The expiry date refers to the last day of that month.

Do not use **Wosulin™-N** and **Wosulin™- 30/70**, if clumps of material are present or if solid white particles stick to the bottom or sides of the cartridge, giving it a frosted appearance. Check this each time you inject yourself

Do not use **Wosulin™-R**, if it is coloured or it has solid particles in it. You must use it only if it looks like water. Check this each time you inject yourself.

- Disposal

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.

Product Description**- What it looks like**

Wosulin™-N appears as a 3 mL cartridge containing a sterile suspension of a white precipitate that is equivalent to 300 IU of human insulin.

Wosulin™-R appears as a 3 mL cartridge containing a colourless liquid, free from turbidity and foreign matter that is equivalent to 300 international units of regular human insulin.

Wosulin™-30/70 appears as a 3 mL cartridge containing a white or almost white suspension containing white or

almost white precipitate that is equivalent to 300 IU of human insulin.

Sambhajinagar-431154, Maharashtra State, India.

- Ingredients

- Active ingredient(s)
WosulinTM products **active substance** is human insulin. Human insulin is made in the laboratory by a 'recombinant DNA technology' process. It has the same structure as the natural hormone made by the pancreas. It is therefore different from animal insulins.

Product Registration Holder

Pharmaniaga LifeScience Sdn Bhd
(198201002939)
Lot 7, Jalan PPU 3, Taman Perindustrian Puchong Utama, 47100 Puchong, Selangor, Malaysia.

Date of revision

19/05/2026

Serial Number

(NPRA (R3) 24/61)

The human insulin in WosulinTM-N is available in a suspension together with protamine sulphate.

WosulinTM-30/70 is a premixed suspension which contains 30 % regular insulin dissolved in water and 70% isophane insulin with protamine sulphate.

- Inactive ingredients

WosulinTM-N and WosulinTM-30/70, Glycerol, Zinc Oxide, m-Cresol, Phenol, Disodium Hydrogen Phosphate, Protamine Sulphate, Sodium Hydroxide (for pH adjustment), Hydrochloric Acid (for pH adjustment), Water for Injection (WFI).

WosulinTM-R, Glycerol, Zinc Oxide, m-Cresol, Tri-Sodium Citrate Dihydrate, Citric Acid Monohydrate, Sodium Hydroxide (for pH adjustment), Hydrochloric Acid (for pH adjustment), Water for Injection (WFI).

- MAL number(s):

WosulinTM-N
MAL24116039AZ

WosulinTM-R
MAL24116038AZ

WosulinTM-30/70
MAL24116040AZ

Manufacturer

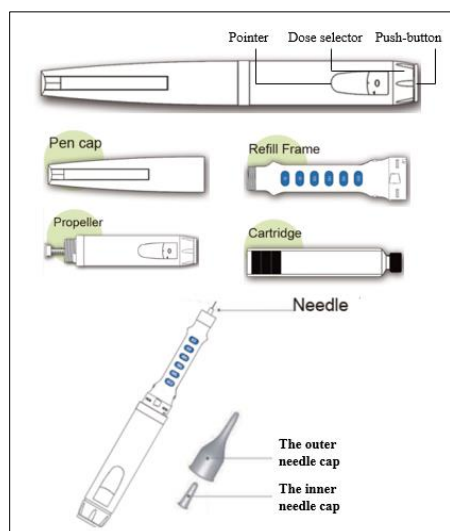
Wockhardt Limited
E-1/1, Wockhardt Infrastructure Development Limited, Special Economic Zone (SEZ), E-1, Shendra MIDC Five Star Industrial Area, Shendra, Chhatrapati

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.

Wosulin™ product can be used with the DELFU pen injector, PENOVVA pen injector and Mypen®2 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.

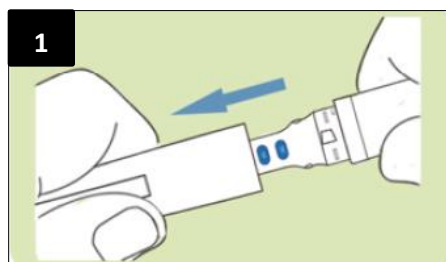
If it is dropped, damaged or crushed, there is a risk of insulin leakage. This may cause inaccurate dosing, which can lead to too high or too low blood sugar level.

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.

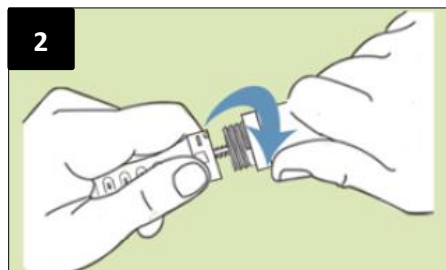
Preparing Pen Injector

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,

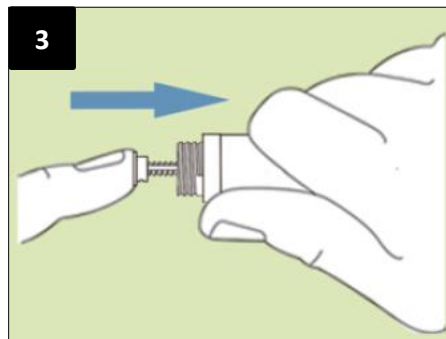
your blood sugar level may get too high or too low.



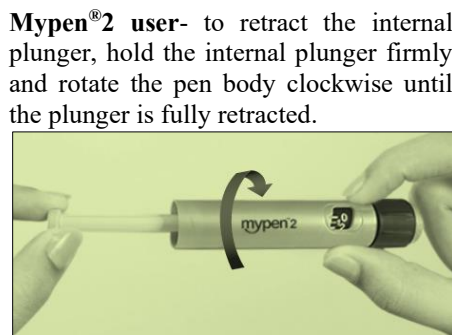
Get the pen from the box, unplug the cap.



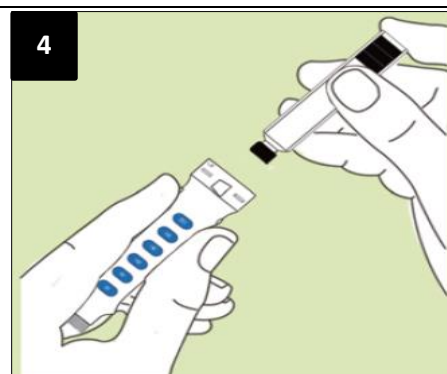
Unscrew the cartridge holder.



Push back the screw until the internal plunger fully retracted.

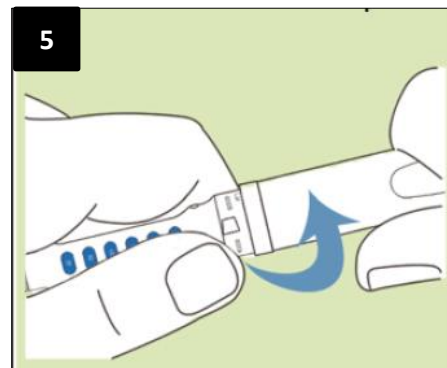


Mypen®2 user- to retract the internal plunger, hold the internal plunger firmly and rotate the pen body clockwise until the plunger is fully retracted.



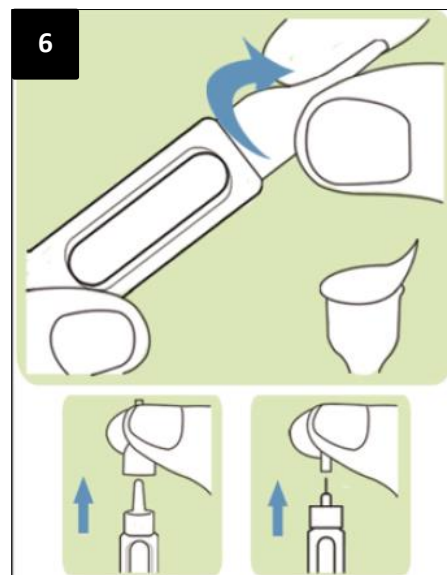
Insert the cartridge into the Refill Frame, putting the small end of the cartridge into the cartridge holder.

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.

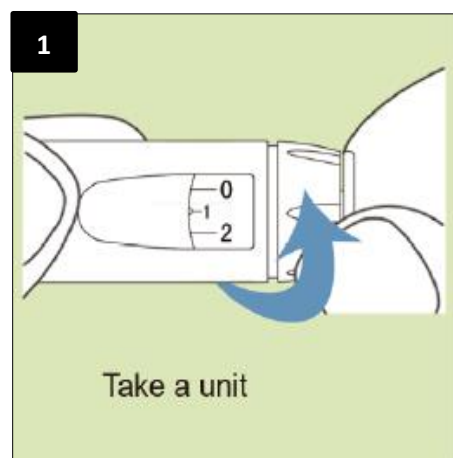
Note: Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

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

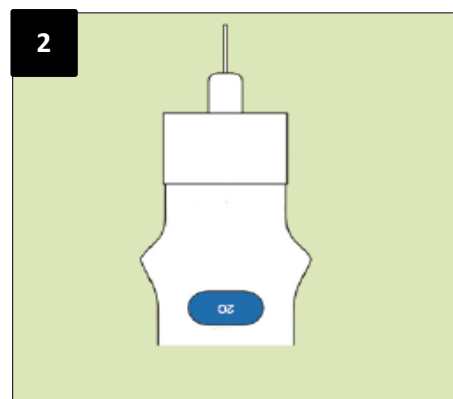
Checking the insulin flow.

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 required to install a new needle.



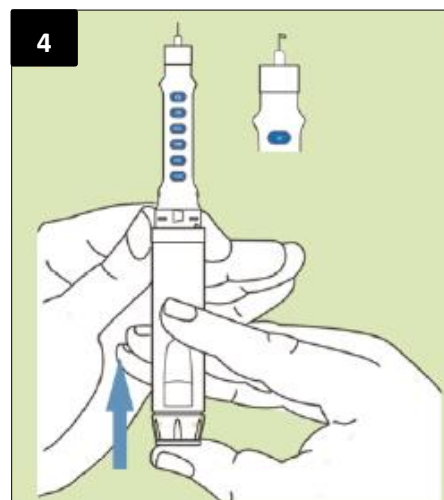
Turn the dose selector, select a dose that you want to inject.



Put the pen vertical and the pen needle upward.

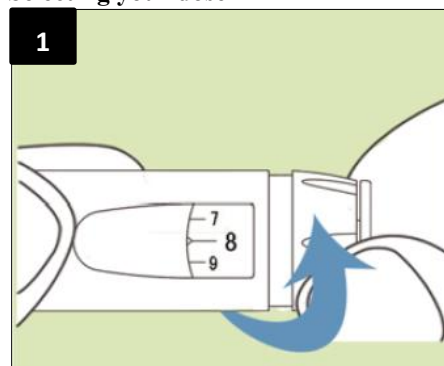


Hold your Pen Injector with the needle pointing upwards and tap the cartridge gently with your finger a few times to make any air bubbles collect at the top of the cartridge.

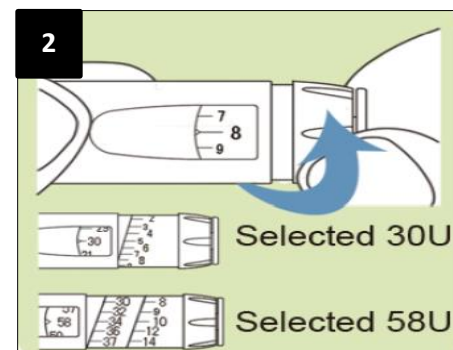


Press the injection button till you see liquid hanging on the tip. If not, change the needle and repeat the procedure. If a drop of insulin still does not appear, the pen is defective, and you must use a new one.

Selecting your dose



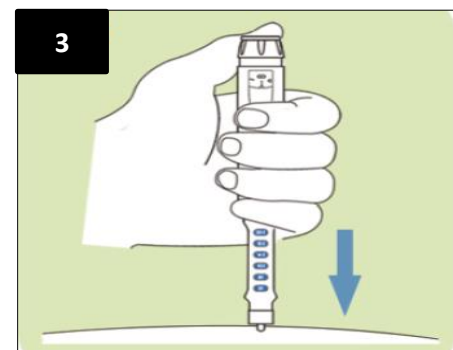
Turn the dose selector to select the number of units you need to inject.



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.

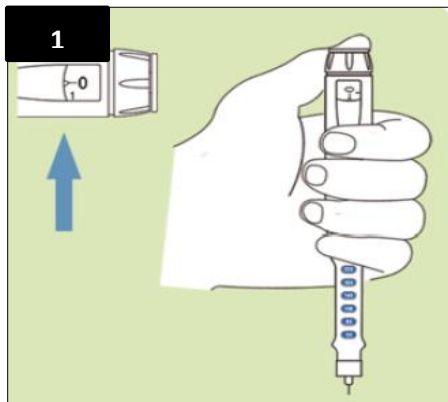


At the end of an injection, the number in the window should be "0", if it is not, this is amount of insulin you did not receive, remember this number, remove the needle and the empty cartridge.

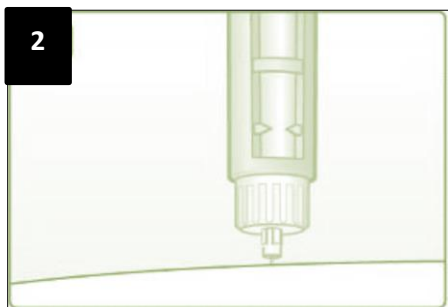
If you select and inject the wrong dose, your blood sugar level may get too high or too low. Do not use the residual scale, it only shows approximately how much insulin is left in your pen.

Making the injection

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



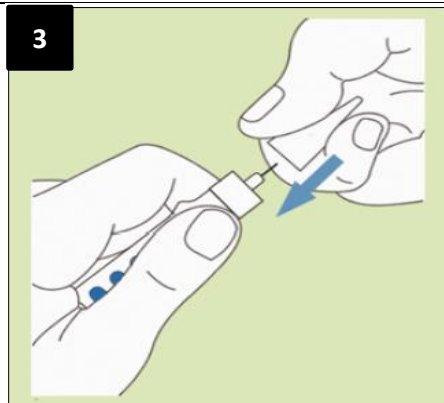
Inject the dose by pressing the push-button all the way in until 0 lines up with the pointer. Be careful only to push the push-button when injecting.



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.