

# Basalin

## 100 Units/mL Solution for Injection<sup>®</sup>

Insulin glargine (100 units/ml)

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### What Basalin is used for

Basalin is used to treat diabetes mellitus in adults, adolescents and children age 2 years and above.

Diabetes mellitus is a disease where your body does not produce enough insulin to control the level of blood sugar.

### How Basalin works

Basalin contains insulin glargine. This is a modified insulin, very similar to human insulin. Insulin glargine has a long and steady blood-sugar-lowering action.

### Before you use Basalin

#### - When you must not use it

Do not take this medicine if:

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

#### - Before you start to use it

#### **Take special care with Basalin**

Follow closely the instructions for dosage, monitoring (blood and urine tests), diet and physical activity (physical work and exercise), injection technique as discussed with your doctor.

If your blood sugar is too low (hypoglycaemia), follow the guidance for hypoglycaemia (see HYPERGLYCAEMIA AND HYPOGLYCAEMIA at the end of this leaflet).

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 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.

#### Travel

Before travelling consult your doctor. You may need to talk about

- the availability of your insulin in the country you are visiting,
- supplies of insulin, syringes etc.
- correct storage of your insulin while travelling,
- timing of meals and insulin administration while travelling,
- the possible effects of changing to different time zones,
- possible new health risks in the countries to be visited,
- what you should do in emergency situations when you feel unwell or become ill.

#### Illnesses and injuries

In the following situations, the management of your diabetes may require a lot of care (for example, adjustment to insulin dose, blood and urine tests):

- If you are ill or have a major injury then your blood sugar level may increase (hyperglycaemia).
- If you are not eating enough your blood sugar level may become too low (hypoglycaemia).

In most cases you will need a doctor.

#### **Make sure that you contact a doctor early.**

If you have type 1 diabetes (insulin dependent diabetes mellitus), do not stop your insulin and continue to get enough carbohydrates. Always tell people who are caring for you or treating you that you require insulin.

#### Pregnancy and lactation

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

need to be changed during pregnancy and after giving birth. Particularly careful control of your diabetes, and prevention of hypoglycaemia, is important for the health of your baby.

If you are breast-feeding consult your doctor as you may require adjustments in your insulin doses and your diet.

#### - Taking other medicines

Some medicines cause changes in the blood sugar level (decrease, increase or both depending on the situation). In each case, it may be necessary to adjust your insulin dose to avoid blood sugar levels that are too low or too high. Be careful when you start or stop taking another medicine.

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. Before taking a medicine ask your doctor if it can affect your blood sugar level and what action, if any, you need to take.

#### Medicines that may cause your blood sugar level to fall (hypoglycaemia) include:

- all other medicines to treat diabetes,
- angiotensin converting enzyme (ACE) inhibitors (used to treat certain heart conditions or high blood pressure),
- disopyramide (used to treat certain heart conditions),
- fluoxetine (used to treat depression),
- fibrates (used to lower high levels of blood lipids),
- monoamine oxidase (MAO) inhibitors (used to treat depression),
- pentoxifylline, propoxyphene, salicylates (such as aspirin, used to relieve pain and lower fever),
- sulfonamide antibiotics.

#### Medicines that may cause your blood sugar level to rise (hyperglycaemia) include:

- corticosteroids (such as "cortisone" used to treat inflammation),

-danazol (medicine acting on ovulation),  
 - diazoxide (used to treat high blood pressure),  
 - diuretics (used to treat high blood pressure or excessive fluid retention),  
 - glucagon (pancreas hormone used to treat severe hypoglycaemia),  
 - isoniazid (used to treat tuberculosis),  
 - oestrogens and progestogens (such as in the contraceptive pill used for birth control),  
 - phenothiazine derivatives (used to treat psychiatric disorders),  
 - somatropin (growth hormone),  
 - sympathomimetic medicines (such as epinephrine [adrenaline], or salbutamol, terbutaline used to treat asthma),  
 - thyroid hormones (used to treat thyroid gland disorders),  
 - atypical antipsychotic medicines (such as clozapine, olanzapine),  
 - protease inhibitors (used to treat HIV).

Your blood sugar level may either rise or fall if you take:

- beta-blockers (used to treat high blood pressure),  
 - clonidine (used to treat high blood pressure),  
 - lithium salts (used to treat psychiatric disorders).

Pentamidine (used to treat some infections caused by parasites) may cause hypoglycaemia which may sometimes be followed by hyperglycaemia.

Beta-blockers like other sympatholytic medicines (such as clonidine, guanethidine, and reserpine) may weaken or suppress entirely the first warning symptoms which help you to recognise a hypoglycaemia. If you are not sure whether you are taking one of those medicines ask your doctor or pharmacist.

### Using Basalin with food and drink

Your blood sugar levels may either rise or fall if you drink alcohol.

### Important information about some of the ingredients of Basalin

This medicine contains less than 1 mmol (23 mg) sodium per dose, i.e. it is essentially 'sodium-free'.

### How to use Basalin

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### - How much to use

Based on your life-style and the results of your blood sugar (glucose) tests and your previous insulin usage, your doctor will

- determine how much Basalin per day you will need and at what time.
- tell you when to check your blood sugar level, and whether you need to carry out urine tests,
- tell you when you may need to inject a higher or lower dose of Basalin.

Basalin is a long-acting insulin. Your doctor may tell you to use it in combination with a short-acting insulin or with tablets used to treat high blood sugar levels.

Many factors may influence your blood sugar level. You should know these factors so that you are able to react correctly to changes in your blood sugar level and to prevent it from becoming too high or too low. See HYPERGLYCAEMIA AND HYPOGLYCAEMIA at the end of this leaflet for further information.

### Use in children

Basalin can be used in adolescents and children of 2 years and above.

#### - When to use it

Use as directed by your doctor or pharmacist.

#### - How long to use it

Use Basalin for the duration that the doctor recommends.

### Method of administration

Basalin is injected under the skin. Do NOT inject Basalin in a vein, since this will change its action and may cause hypoglycaemia.

Your doctor will show you in which area of the skin you should inject Basalin. With each injection, change the puncture site within the particular area of skin that you are using.

Basalin is to be used with DELFU Pen Injector (reusable) and should not be used with any other reusable pen as the dosing accuracy has not been established with other pens.

A safety test must be performed before each injection.

Look at the cartridge before you use it. Do not use Basalin if you notice particles in it. Only use Basalin if the solution is clear, colourless and waterlike. Do not shake or mix it before use.

#### - If you forget to use it

If you have missed a dose of Basalin or if you have not injected enough insulin, your blood sugar level may become too high (hyperglycaemia). Check your blood sugar frequently. For information on the treatment of hyperglycaemia, see HYPERGLYCAEMIA AND HYPOGLYCAEMIA at the end of this leaflet.

- Do not take a double dose to make up for a forgotten dose.

#### - 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 use 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 have injected too much Basalin, your blood sugar level may become too low (hypoglycaemia). Check your blood sugar frequently. In general, to prevent hypoglycaemia you must eat more food and monitor your blood sugar. For information on the treatment of hypoglycaemia, see HYPERGLYCAEMIA AND HYPOGLYCAEMIA at the end of this leaflet.

### If you stop using Basalin

This could lead to severe hyperglycaemia (very high blood

sugar) and ketoacidosis (build-up of acid in the blood because the body is breaking down fat instead of sugar). Do not stop Basalin without speaking to a doctor, who will tell you what needs to be done.

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

#### **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 Basalin.

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

Take Basalin only with a doctor's prescription.

##### **- 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 Basalin 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 or react may be reduced if:

- you have hypoglycaemia (low blood sugar levels),
- you have hyperglycaemia (high blood sugar levels),
- you have problems with your sight.

Keep this possible problem in mind in all situations where you might put yourself and others at risk (such as driving a car or operating machines). You should contact your doctor for advice on driving if:

- you have frequent episodes of hypoglycaemia,
- the first warning symptoms which help you to recognise hypoglycaemia are reduced or absent.

#### **Insulin mix-ups**

You must always check the insulin label before each injection to avoid mix-ups between Basalin and other insulins.

#### **Side effects**

Like all medicines, Basalin can cause side effects, although not everybody gets them.

**If you notice signs of your blood sugar being too low (hypoglycaemia),** take action to increase your blood sugar level straight away (see the end of this leaflet). Hypoglycaemia (low blood sugar) can be very serious and is very common with insulin treatment (may affect more than 1 in 10 people). Low blood sugar means that there is not enough sugar in your blood. If your blood sugar level falls too low, you may pass out (become unconscious). Serious hypoglycaemia may cause brain damage and may be life-threatening.

**Severe allergic reactions (rare, may affect up to 1 in 1,000 people)** – the signs may include large-scale skin reactions (rash and itching all over the body), severe swelling of skin or mucous membranes (angioedema), shortness of breath, a fall in blood pressure with rapid heartbeat and sweating. Severe allergic reactions to insulins may become life-threatening. Tell a doctor straight away if you notice signs of severe allergic reaction.

#### **Other side effects:**

##### **• Skin changes at the injection site**

If you inject your insulin too often at the same place, the skin may either shrink (lipoatrophy, *may affect up to 1 in 100 people*) or thicken (lipohypertrophy, *may affect up to 1 in 10 people*). Lumps under the skin may also be caused by build-up of a protein called amyloid.

Frequency 'not known': Changes at the injection site (Cutaneous amyloidosis). The insulin may not work very well if you inject into lumpy area. Change the injection site with each injection to help prevent these skin changes.

**Common reported side effects** (may affect up to 1 in 10 people)

##### **• Skin and allergic reactions at the injection site**

The signs may include reddening, unusually intense pain when injecting, itching, hives, swelling or inflammation. This can spread around the injection site. Most minor reactions to insulins usually disappear in a few days to a few weeks.

**Rare reported side effect** (may affect up to 1 in 1,000 people)

##### **• Eye reactions**

A marked change (improvement or worsening) in your blood sugar control can disturb your vision temporarily. If you have proliferative retinopathy (an eye disease related to diabetes) severe hypoglycaemic attacks may cause temporary loss of vision.

##### **• General disorders**

In rare cases, insulin treatment may also cause temporary build-up of water in the body, with swelling in the calves and ankles.

#### **Use in children and adolescents**

In general, the side effects in children and adolescents of 18 years of age or less are similar to those seen in adults.

Complaints of injection site reactions (injection site reaction, injection site pain) and skin reactions (rash, urticaria) are reported relatively more frequently in children and adolescents of 18 years of age or less than in adults. There is no experience in children under 2 years.

**Very rare reported side-effects** (may affect up to 1 in 10,000 people) In very rare cases, dysgeusia (taste disorders) and myalgia (muscular pain) can occur.

Talk to your doctor or pharmacist if any of the side effects gets serious or lasts longer than a few days or if you notice any side effects not listed in this leaflet.

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](http://npra.gov.my) [Consumers→ Reporting

Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

### Storage and Disposal of Basalin

#### - Storage

Keep out of the reach and sight of children.

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

#### Not in-use cartridge.

Store Basalin in a refrigerator (2°C – 8°C). **Do not freeze** or place next to the freezer compartment or a freezer pack. Keep the cartridge in the outer carton in order to protect from light.

#### In use cartridge

Stored for a maximum of 4 weeks not above 30°C and away from direct heat or direct light. The pen in use must not be stored in the refrigerator. The pen cap must be put back on the pen after each injection in order to protect from light. Do not use it after this time period.

#### - 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

Basalin 100 units/ml solution for injection in a cartridge, is a clear and colourless solution. Each cartridge contains 3 ml of solution for injection (equivalent to 300 units).

#### - Ingredients

##### - Active ingredient(s)

Each ml of the solution contains 100 units of the active substance insulin glargine (equivalent to 3.64 mg).

##### - Inactive ingredients

Zinc chloride, Metacresol, Glycerol, Hydrochloric acid (for pH adjustment), Sodium hydroxide (for

pH adjustment) and Water for injections.

#### - MAL number(s):

Basalin 100 Units/mL Solution for Injection  
MAL25016117AZ

#### **Manufacturer**

Gan & Lee Pharmaceuticals  
No. 8 Nanfeng West 1st Street, Huoxian,  
Tongzhou District, Beijing,  
China.

#### **Product Registration Holder**

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

#### **Date of revision**

21/01/2025

#### **Serial Number**

NPRA(R3)24/75

### HYPERGLYCAEMIA AND HYPOGLYCAEMIA

**Always carry some sugar (at least 20 grams) with you.**

**Carry some information with you to show you are diabetic.**

#### HYPERGLYCAEMIA (high blood sugar levels)

**If your blood sugar is too high (hyperglycaemia), you may not have injected enough insulin. Why does hyperglycaemia occur?**

Examples include:

- you have not injected your insulin or not injected enough, or if it has become less effective, for example through incorrect storage,
- your insulin pen does not work properly,
- you are doing less exercise than usual, you are under stress (emotional distress, excitement), or you have an injury, operation, infection or fever,
- you are taking or have taken certain other medicines (see *Taking other medicines*).

#### **Warning symptoms of hyperglycaemia**

Thirst, increased need to urinate, tiredness, dry skin, reddening of the face, loss of appetite, low blood pressure, fast heartbeat, and glucose and ketone bodies in urine. Stomach pain, fast and deep breathing, sleepiness or even loss of consciousness may be signs of a serious condition (ketoacidosis) resulting from lack of insulin.

#### **What should you do if you experience hyperglycaemia?**

**Test your blood sugar level and your urine for ketones as soon as any of the above symptoms occur.** Severe hyperglycaemia or ketoacidosis must always be treated by a doctor, normally in a hospital.

#### HYPOGLYCAEMIA (low blood sugar levels)

If your blood sugar level falls too much you may become unconscious. Serious hypoglycaemia may cause a heart attack or brain damage and may be life threatening. You normally should be able to recognise when your blood sugar is falling too much so that you can take the right actions.

#### **Why does hypoglycaemia occur?**

Examples include:

- you inject too much insulin,
- you miss meals or delay them,
- you do not eat enough, or eat food containing less carbohydrate than normal (sugar and substances similar to sugar are called carbohydrates; however, artificial sweeteners are NOT carbohydrates),
- you lose carbohydrates due to vomiting or diarrhoea,
- you drink alcohol, particularly if you are not eating much,
- you are doing more exercise than usual or a different type of physical activity,
- you are recovering from an injury or operation or other stress,
- you are recovering from an illness or from fever,
- you are taking or have stopped taking certain other medicines (see *Taking other medicines*).

#### **Hypoglycaemia is also more likely to occur if**

- you have just begun insulin treatment

or changed to another insulin preparation (when changing from your previous basal insulin to Basalin, hypoglycaemia, if it occurs, may be more likely to occur in the morning than at night),

- your blood sugar levels are almost normal or are unstable,
- you change the area of skin where you inject insulin (for example from the thigh to the upper arm),
- you suffer from severe kidney or liver disease, or some other disease such as hypothyroidism.

### **Warning symptoms of hypoglycaemia**

- In your body

Examples of symptoms that tell you that your blood sugar level is falling too much or too fast: sweating, clammy skin, anxiety, fast heartbeat, high blood pressure, palpitations and irregular heartbeat. These symptoms often develop before the symptoms of a low sugar level in the brain.

- In your brain

Examples of symptoms that indicate a low sugar level in the brain: headaches, intense hunger, nausea, vomiting, tiredness, sleepiness, sleep disturbances, restlessness, aggressive behaviour, lapses in concentration, impaired reactions, depression, confusion, speech disturbances (sometimes total loss of speech), visual disorders, trembling, paralysis, tingling sensations (paraesthesia), numbness and tingling sensations in the area of the mouth, dizziness, loss of self-control, inability to look after yourself, convulsions, loss of consciousness.

The first symptoms which alert you to hypoglycaemia ("warning symptoms") may change, be weaker or may be missing altogether if

- you are elderly, if you have had diabetes for a long time or if you suffer from a certain type of nervous disease (diabetic autonomic neuropathy),
- you have recently suffered hypoglycaemia (for example the day before) or if it develops slowly
- you have almost normal or, at least, greatly improved blood sugar levels,
- you have recently changed from an animal insulin to a human insulin such as Basalin,
- you are taking or have taken certain

other medicines (see *Taking other medicines*).

In such a case, you may develop severe hypoglycaemia (and even faint) before you are aware of the problem. Be familiar with your warning symptoms. If necessary, more frequent blood sugar testing can help to identify mild hypoglycaemic episodes that might otherwise be overlooked. If you are not confident about recognising your warning symptoms, avoid situations (such as driving a car) in which you or others would be put at risk by hypoglycaemia.

### **What should you do if you experience hypoglycaemia?**

1. Do not inject insulin. Immediately take about 10 to 20 g sugar, such as glucose, sugar cubes or a sugar sweetened beverage. Caution: Artificial sweeteners and foods with artificial sweeteners (such as diet drinks) are of no help in treating hypoglycaemia.

2. Then eat something that has a long acting effect in raising your blood sugar (such as bread or pasta). Your doctor or nurse should have discussed this with you previously. The recovery of hypoglycaemia may be delayed because Basalin has a long action.

3. If the hypoglycaemia comes back again, take another 10 to 20 g sugar.

4. Speak to a doctor immediately if you are not able to control the hypoglycaemia or if it recurs.

Tell your relatives, friends, and close colleagues the following:

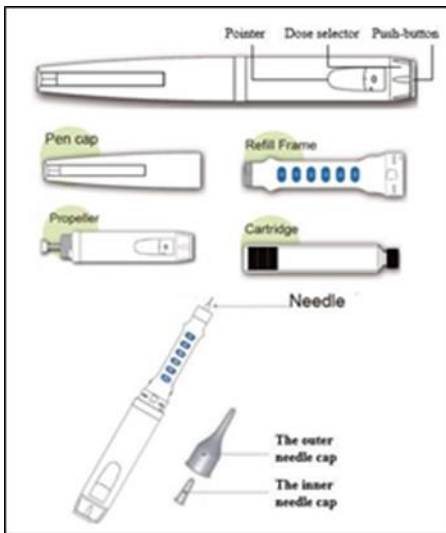
If you are not able to swallow or if you are unconscious, you will require an injection of glucose or glucagon (a medicine which increases blood sugar). These injections are justified even if it is not certain that you have hypoglycaemia.

It is advisable to test your blood sugar immediately after taking glucose to check that you really have hypoglycaemia.

## 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.

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

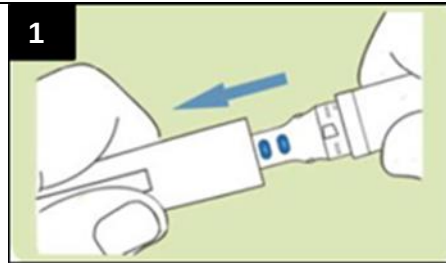
Your Pen Injector must be handled with care.

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.

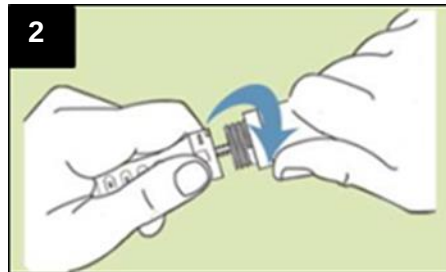
You can clean the exterior of your Pen Injector by wiping it with a medicinal swab. Do not soak it, wash or lubricate it as it may damage the pen.

### Preparing Pen Injector

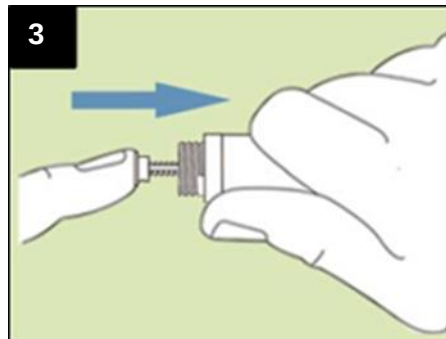
Check the name of insulin cartridge to make sure that it contains the correct type of insulin. This is especially important if you take more than one type of insulin. If you take more than one type of insulin, your blood sugar level may get too high or too low



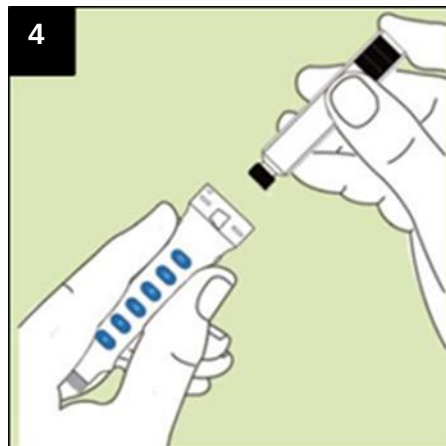
Get the pen from the box, unplug the cap.



Unscrew the cartridge holder.

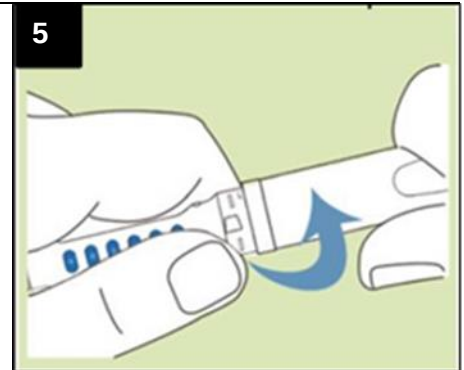


Push back the screw until the internal plunger fully retracted



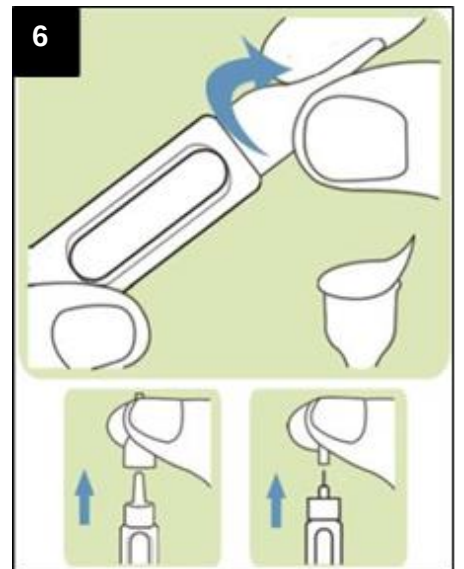
Insert the cartridge into the Refill Frame, putting the small end of the cartridge into the cartridge holder.

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.

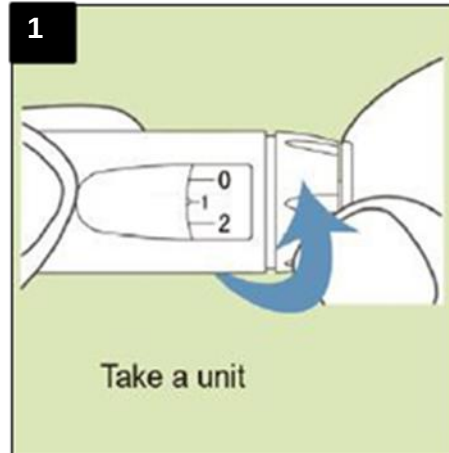
Note: Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of insulin, blocked needles and inaccurate dosing.

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

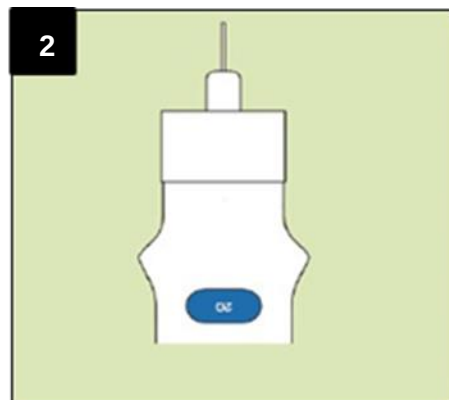
## Checking the insulin flow.

**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 is required to install a new needle.



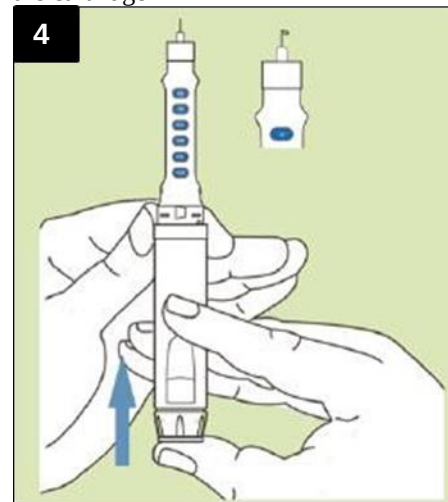
Turn the dose selector, select a dose that you want to inject.



Put the pen vertical and the pen needle upward

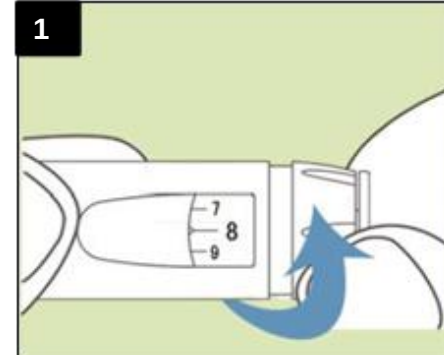


Hold your Pen Injector with the needle pointing upwards and tap the cartridge gently with your finger a few times to make any air bubbles collect at the top of the cartridge

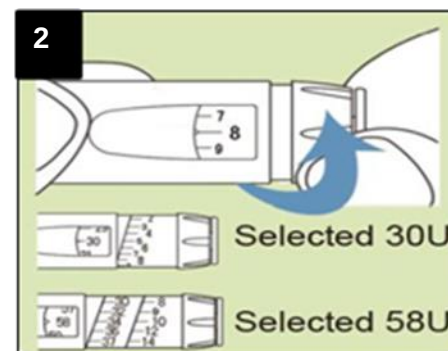


Press the injection button till you see liquid hanging on the tip. If not, change the needle and repeat the procedure. If a drop of insulin still does not appear, the pen is defective, and you must use a new one

## Selecting your dose



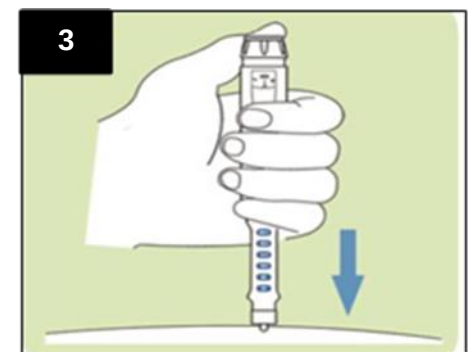
Turn the dose selector to select the number of units you need to inject



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

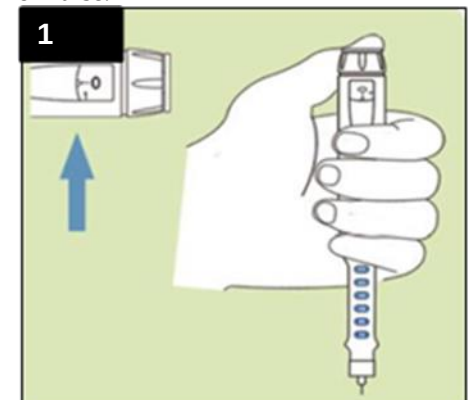


At the end of an injection, the number in the window should be "0", if it is not, this is amount of insulin you did not receive, remember this number, remove the needle and the empty cartridge.

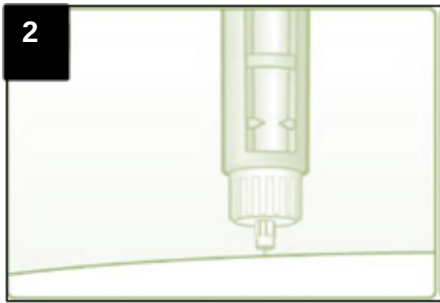
If you select and inject the wrong dose, your blood sugar level may get too high or too low. Do not use the residual scale, it only shows approximately how much insulin is left in your pen.

## Making the injection

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



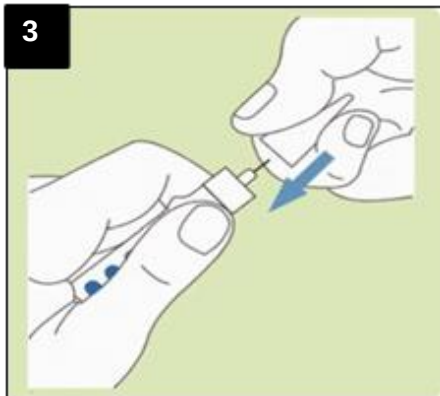
Inject the dose by pressing the push-button all the way in until 0 lines up with the pointer. Be careful only to push the push-button when injecting.



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.