Package leaflet: Information for the user

Liraglutide STADA Arzneimittel AG 6 mg/ml solution for injection in pre-filled pen
liraglutide

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
– Keep this leaflet. You may need to read it again.
– If you have any further questions, ask your doctor, pharmacist or nurse.
– This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
– If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What <Invented name> is and what it is used for

<Invented name> contains the active substance liraglutide. It helps your body reduce your blood sugar level only when blood sugar is too high. It also slows food passage through your stomach and can help prevent heart disease.

<Invented name> is used on its own if your blood sugar is not properly controlled by diet and exercise alone, and you cannot use metformin (another diabetes medicine).

<Invented name> is used with other medicines for diabetes when they are not enough to control your blood sugar levels. These may include:
• oral antidiabetics (such as metformin, pioglitazone, sulfonylurea, sodium-glucose cotransporter 2 inhibitor (SGLT2i)) and/or insulin.

2. What you need to know before you use <Invented name>

Do not use <Invented name>
– if you are allergic to liraglutide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions
Talk to your doctor, pharmacist or nurse:
• before using <Invented name>.
• if you have or have had a disease of the pancreas.

If you know that you are due to have surgery where you will be under anesthesia (sleeping), please tell your doctor that you are taking <Invented name>.

This medicine should not be used if you have type 1 diabetes (your body does not produce any insulin)

or diabetic ketoacidosis (a complication of diabetes with high blood sugar and increase in effort to breathe). It is not an insulin and should therefore not be used as a substitute for insulin.

The use of <Invented name> is not recommended if you are on dialysis.
The use of <Invented name> is not recommended if you have severe liver disease.
The use of <Invented name> is not recommended if you have severe heart failure.

This medicine is not recommended if you have a severe stomach or gut problem which results in delayed stomach emptying (called gastroparesis), or inflammatory bowel disease.

If you have symptoms of acute pancreatitis, such as persistent, severe stomach ache, you should consult your doctor immediately (see section 4).

If you have thyroid disease including thyroid nodules and enlargement of the thyroid gland, consult your doctor.

When initiating treatment with <Invented name>, you may in some cases experience loss of fluids/dehydration, e.g. in case of vomiting, nausea and diarrhoea. It is important to avoid dehydration by drinking plenty of fluids. Contact your doctor if you have any questions or concerns.

Children and adolescents
<Invented name> can be used in adolescents and children aged 10 years and above. No data are available in children below 10 years of age.

Other medicines and <invented name>
Please tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines.

In particular, tell your doctor, pharmacist or nurse if you are using medicines containing any of the following active substances:
- Sulfonylurea (such as glimepiride or glibenclamide) or insulin. You may get hypoglycaemia (low blood sugar) when using <Invented name> together with a sulfonylurea or insulin, as sulfonylureas and insulin increase the risk of hypoglycaemia. When you first start using these medicines together, your doctor may tell you to lower the dose of the sulfonylurea or insulin. Please see section 4 for the warning signs of low blood sugar. If you are also taking a sulfonylurea (such as glimepiride or glibenclamide) or insulin, your doctor may tell you to test your blood sugar levels. This will help your doctor to decide if the dose of the sulfonylurea or insulin needs to be changed.
- If you are using insulin, your doctor will tell you how to reduce the dose of insulin and will recommend you to monitor your blood sugar more frequently, in order to avoid hyperglycaemia (high blood sugar) and diabetic ketoacidosis (a complication of diabetes that occurs when the body is unable to break down glucose because there is not enough insulin).
- Warfarin or other oral anti-coagulation medicines. More frequent blood testing to determine the ability of your blood to clot may be required.

Pregnancy and breast-feeding
Tell your doctor if you are, you think you might be, or are planning to become pregnant. <Invented name> should not be used during pregnancy because it is not known if it may harm your unborn child.

It is not known if <Invented name> passes into breast milk, therefore do not use this medicine if you are breast- feeding.

Driving and using machines
Low blood sugar (hypoglycaemia) may reduce your ability to concentrate. Avoid driving or using machines if you experience signs of hypoglycaemia. Please see section 4 for the warning signs of low blood sugar. Please consult your doctor for further information on this topic.

<Invented name> contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per dose. This means that it is essentially 'sodium free'.

3. How to use <Invented name>

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

- The starting dose is 0.6 mg once a day, for at least one week.
- Your doctor will tell you when to increase it to 1.2 mg once a day.
- Your doctor may tell you to further increase the dose to 1.8 mg once a day, if your blood glucose is not adequately controlled with a dose of 1.2 mg.

Do not change your dose unless your doctor has told you to.

<Invented name> is given as an injection under the skin (subcutaneous). Do not inject it into a vein or muscle. The best places to give yourself the injection are the front of your thighs, the front of your waist (abdomen), or your upper arm. Change the place where you inject each day to reduce the risk of developing lumps.

You can give yourself the injection at any time of the day, regardless of meals. When you have found the most convenient time of the day it is preferred that you inject <Invented name> around the same time of the day.

Before you use the pen for the first time, your doctor or nurse will show you how to use it.
Detailed instructions for use are provided on the other side of this leaflet.

If you use more <Invented name> than you should
If you use more <Invented name> than you should, talk to your doctor straight away. You may need medical treatment. You may experience nausea, vomiting, diarrhoea or low blood sugar (hypoglycaemia). Please refer to section 4 for warning signs of low blood sugar.

If you forget to use <Invented name>
If you forget a dose, use <Invented name> as soon as you remember.
However, if it is more than 12 hours since you should have used <Invented name>, skip the missed dose. Then take your next dose as usual the following day.
Do not take an extra dose or increase the dose on the following day to make up for the missed dose.

If you stop using <Invented name>
Do not stop using <Invented name> without talking to your doctor. If you stop using it, your blood sugar levels may increase.

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

4. Possible side effects

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

Serious side effects
Common: may affect up to 1 in 10 people

- Hypoglycaemia (low blood sugar). The warning signs of low blood sugar may come on suddenly and can include: cold sweat, cool pale skin, headache, fast heartbeat, feeling sick, feeling very hungry, changes in vision, feeling sleepy, feeling weak, nervous, anxious, confused, difficulty concentrating, shaking (tremor). Your doctor will tell you how to treat low blood sugar and what to do if you notice these warning signs. This is more likely to happen if you also take a sulfonylurea or insulin. Your doctor may reduce your dose of these medicines before you start using <Invented name>.

Rare: may affect up to 1 in 1,000 people
- A severe form of allergic reaction (anaphylactic reaction) with additional symptoms such as breathing problems, swelling of throat and face, fast heartbeat, etc. If you experience these symptoms you should seek immediate medical help and inform your doctor as soon as possible.
- Bowel obstruction. A severe form of constipation with additional symptoms such as stomach ache, bloating, vomiting etc.

Very rare: may affect up to 1 in 10,000 people
- Cases of inflammation of the pancreas (pancreatitis). Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking <Invented name> and contact a doctor immediately if you notice any of the following serious side effects:

  Severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting, as it could be a sign of an inflamed pancreas (pancreatitis).

Other side effects
Very common: may affect more than 1 in 10 people
- Nausea (feeling sick). This usually goes away over time.
- Diarrhoea. This usually goes away over time.

Common: may affect up to 1 in 10 people
- Vomiting.

When initiating treatment with <Invented name>, you may in some cases experience loss of fluids/dehydration, e.g. in case of vomiting, nausea and diarrhoea. It is important to avoid dehydration by drinking plenty of fluids.

- Headache
- Indigestion
- Inflamed stomach (gastritis). The signs include stomach ache, nausea and vomiting.
- Gastro-oesophageal reflux disease (GORD). The signs include heartburn.
- Painful or swollen tummy (abdomen)
- Abdominal discomfort
- Constipation
- Wind (flatulence)
- Decreased appetite
- Bronchitis
- Common cold
- Dizziness
- Increased pulse
- Tiredness
- Toothache
- Injection site reactions (such as bruising, pain, irritation, itching and rash)
- Increase of pancreatic enzymes (such as lipase and amylase).

Uncommon: may affect up to 1 in 100 people
- Allergic reactions like pruritus (itching) and urticaria (a type of skin rash)
- Dehydration, sometimes with a decrease in kidney function
- Malaise (feeling unwell)
- Gallstones
- Inflamed gallbladder
- Change in how things taste
- A delay in the emptying of the stomach.

Not known: frequency cannot be estimated from the available data
• Lumps under the skin may be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Invented name>

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pen label and carton after 'EXP'. The expiry date refers to the last day of that month.

Before opening:
Store in a refrigerator (2ºC–8ºC). Do not freeze.

During use:
You can keep the pen for 1 month when stored at a temperature below 30ºC or in a refrigerator (2ºC–8ºC). Do not freeze.
When you are not using the pen, keep the pen cap on in order to protect from light.

Do not use this medicine if the solution is not clear, colourless and free from visible particles.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What <Invented name> contains
– The active substance is liraglutide. 1 ml solution for injection contains 6 mg liraglutide. One pre-filled pen contains 18 mg liraglutide.The other ingredients are disodium phosphate dihydrate, propylene glycol (E-1520), phenol, hydrochloric acid (for pH adjustment), sodium hydroxide (for pH adjustment) and water for injections.

What <Invented name> looks like and contents of the pack
<Invented name> is supplied as a clear, colourless, free from visible particles solution for injection in a pre-filled pen (injection). Each pen contains 3 ml of solution, delivering 30 doses of 0.6 mg, 15 doses of 1.2 mg or 10 doses of 1.8 mg.
<Invented name> is available in packs containing 1, 2, 3, 5 or 10 pens. Not all pack sizes may be marketed. Needles are not included.

Marketing Authorisation Holder
<[To be completed nationally]>

Manufacturer

<[To be completed nationally]>

This leaflet was last revised in 2026-05-12

Other sources of information

<[To be completed nationally]>

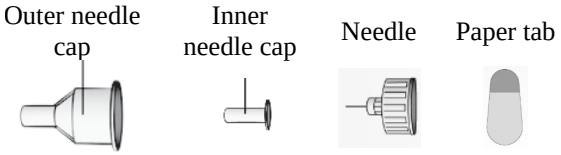
INSTRUCTIONS FOR USING THE <Invented name> **PEN**

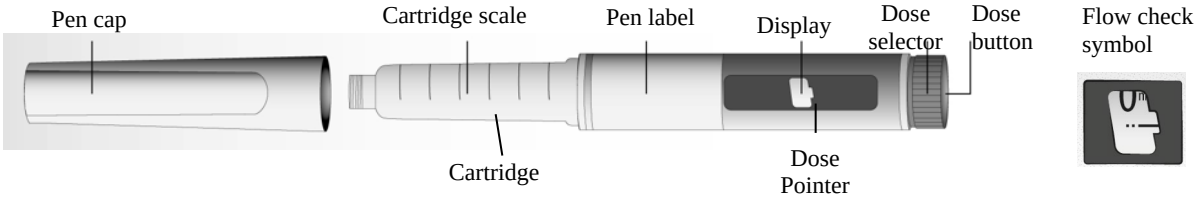
Please read these instructions carefully before using your pen.

Your pen comes with 18 mg of liraglutide. You can select doses of 0.6 mg, 1.2 mg and 1.8 mg.

The pen is designed to be used with disposable injection needles up to a length of 8 mm and as thin as 32G (0.25/0.23 mm).

Needle (Example)

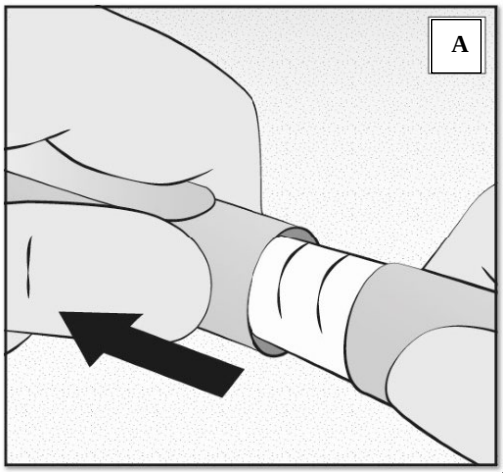




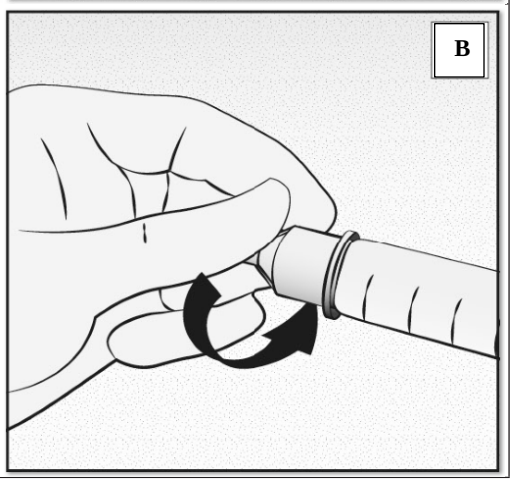
Prepare your pen

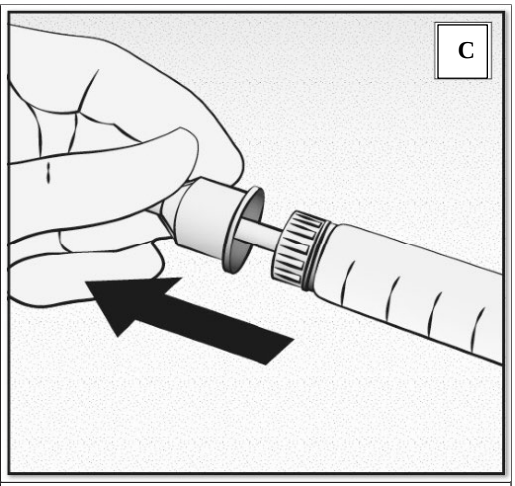
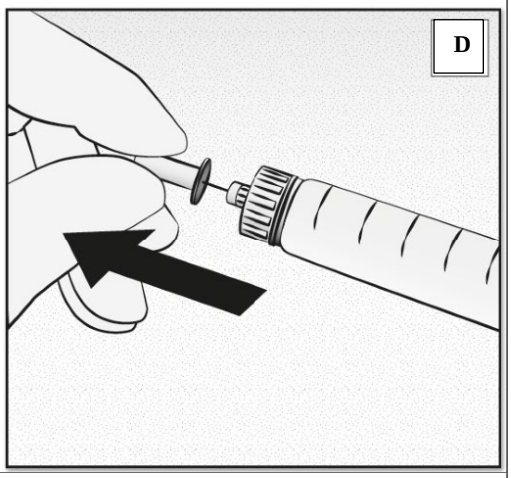
Check the name of your pen to make sure that it contains liraglutide. Using the wrong medicine could cause severe harm.

Pull off the pen cap.



Pull off the paper tab from a new disposable needle.
Screw the needle straight and tightly onto your pen.



Pull off the outer needle cap and keep it for later.	
Pull off the inner needle cap and dispose of it.	

⚠ Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of liraglutide, blocked needles and inaccurate dosing.
⚠ Be careful not to bend or damage the needle.
⚠ Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.

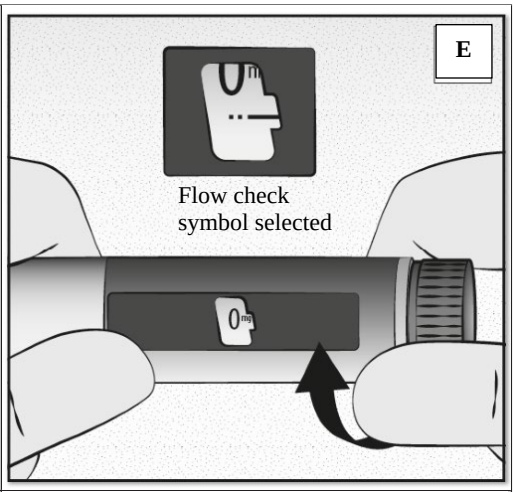
Caring for your pen
- Do not try to repair your pen or pull it apart.
- Keep your pen away from dust, dirt and all kinds of liquids.
- Clean the pen with a cloth moistened with a mild detergent.
- Do not try to wash, soak or lubricate it – this can harm the pen.

⚠ **Important information**
- Do not share your pen or needles with anyone else.
- Keep your pen out of the reach of others, especially children.
- Change the place where you inject each day to reduce the risk of developing lumps.

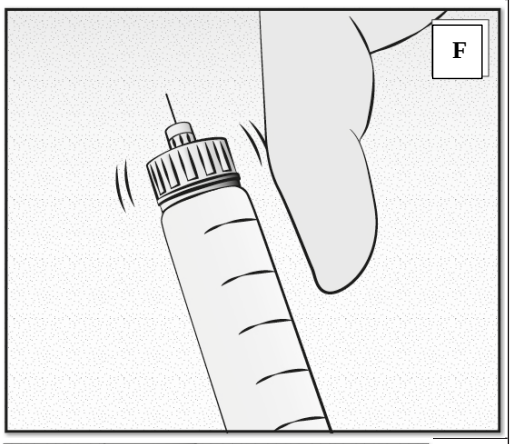
With each new pen, check the flow

Check the flow before your first injection with each new pen. If your pen is already in use, go to 'Select your dose', step H.

Turn the dose selector until the flow check symbol lines up with the pointer.



Hold the pen with the needle pointing up. Tap the cartridge gently with your finger a few times. This will make any air bubbles collect at the top of the cartridge.

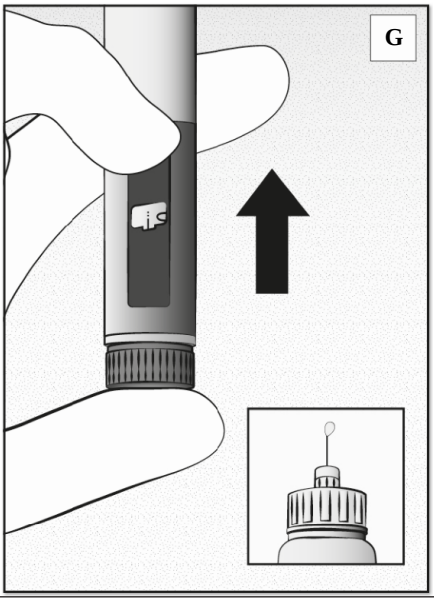


Keep the needle pointing up and press the dose button until 0 mg lines up with the pointer.

A drop of liraglutide should appear at the needle tip. If no drop appears, repeat steps **E** to **G** up to four times.

If there is still no drop of liraglutide, change the needle and repeat steps **E** to **G** once more.

Do not use the pen if a drop of liraglutide still does not appear. This indicates the pen is defective and you must use a new one.



⚠ If you have dropped your pen against a hard surface or suspect that something is wrong with it, always put on a new disposable needle and check the flow before you inject.

Select your dose

Always check that the pointer lines up with 0 mg.

Turn the dose selector until your needed dose lines up with the pointer (0.6 mg, 1.2 mg or 1.8 mg).

If you selected a wrong dose by mistake, simply change it by turning the dose selector backwards or forwards until the right dose lines up with the pointer.

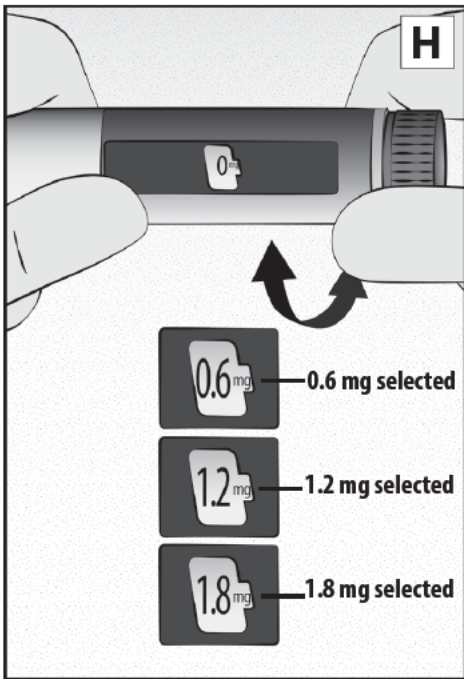
Be careful not to press the dose button when turning the dose selector backwards, as liraglutide may come out.

If the dose selector stops before your needed dose lines up with the pointer, there is not enough liraglutide left for a full dose. Then you can either:

Split your dose into two injections:
Turn the dose selector in either direction until 0.6 mg or 1.2 mg lines up with the pointer. Inject the dose. Then prepare a new pen for injection and inject the remaining number of mg to complete your dose.

You may only split your dose between your current pen and a new pen if trained or advised by your healthcare professional. Use a calculator to plan the doses. If you split the dose wrong, you may inject too much or too little liraglutide.

Inject the full dose with a new pen:
If the dose selector stops before 0.6 mg lines up with the pointer, prepare a new pen and inject the full dose with the new pen.

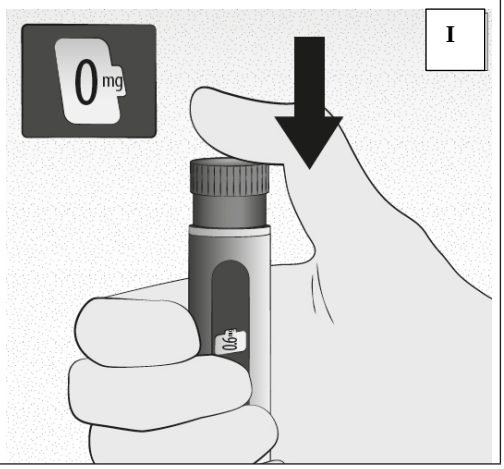


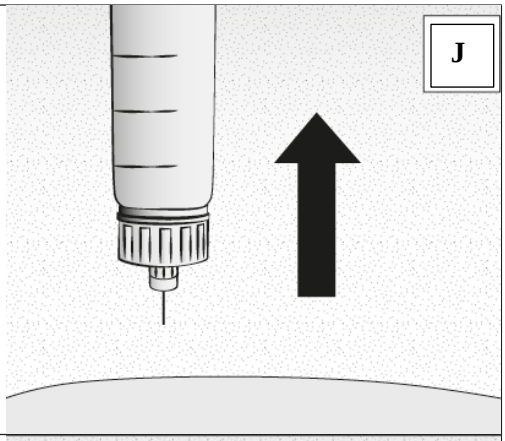
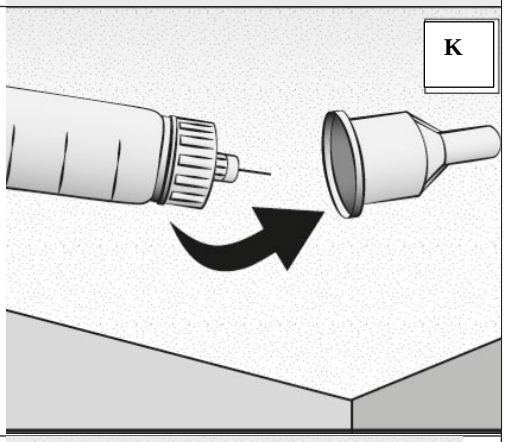
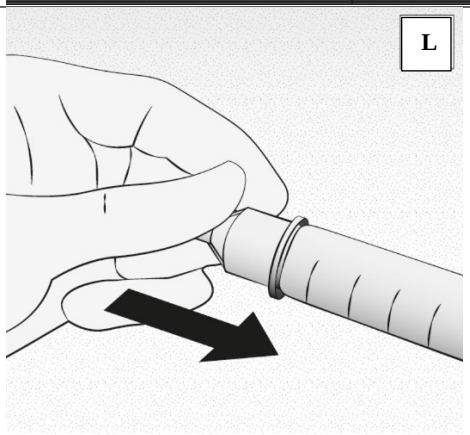
⚠ Do not try to select other doses than 0.6 mg, 1.2 mg or 1.8 mg. The numbers in the display must line up precisely with the pointer to ensure that you get the correct dose.
The dose selector clicks when you turn it. Do not use these clicks to select your dose.
Do not use the cartridge scale to measure how much liraglutide to inject – it is not accurate enough.

Inject your dose

Insert the needle into your skin using the injection technique shown by your doctor or nurse. Then follow the instructions below:

Press the dose button to inject until 0 mg lines up with the pointer. Be careful not to touch the display with your other fingers or press the dose selector sideways when you inject. This is because it may block the injection. Keep the dose button pressed down and leave the needle under the skin for at least 6 seconds. This is to make sure that you get your full dose.



Pull out the needle. After that, you may see a drop liraglutide at the needle tip. This is normal and does not affect your dose.	
Guide the needle tip into the outer needle cap without touching the needle or the outer needle cap.	
When the needle is covered, carefully push the outer needle cap completely on. Then unscrew the needle. Dispose of it carefully and put the pen cap back on. When the pen is empty, carefully dispose of it without a needle attached. Please dispose of the pen and needle in accordance with local requirements.	

⚠ Always remove the needle after each injection, and store your pen without a needle attached.
⚠ This reduces the risk of contamination, infection, leakage of liraglutide, blocked needles and inaccurate dosing.
⚠ Caregivers must be very careful when handling used needles – to prevent needle injury and cross-infection.