APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S4

SAXENDA, 6 mg/ml liraglutide, solution for injection in a pre-filled pen

Read all of this leaflet carefully before you start using SAXENDA

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- SAXENDA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What SAXENDA is and what it is used for
2. What you need to know before you use SAXENDA
3. How to use SAXENDA
4. Possible side effects
5. How to store SAXENDA
6. Contents of the pack and other information

1. What SAXENDA is and what it is used for

Liraglutide is similar to a natural occurring hormone called GLP-1 that is released from the intestine after a meal.

Saxenda is used for chronic weight management in addition to reduced calorie-diet and increased physical activity in adults aged 18 and above who have:

- a Body Mass Index (BMI) of 30 or greater (obesity)

or

- a Body Mass Index (BMI) of 27 and less than 30 (overweight) and weight related health problems (such as diabetes, high blood pressure, abnormal levels of fats in the blood, or breathing problems during sleep called "obstructive sleep apnoea").

BMI (Body Mass Index) is a simple measure of your weight in relation to your height.

Saxenda can be used in adolescents from the age of 12 to below 18 with obesity as diagnosed by your doctor.

Consult with your doctor for the use of Saxenda in adolescents aged 12 to below 18 years.

2. What you need to know before you use SAXENDA

Do not administer SAXENDA:

- If you are allergic to liraglutide or any of the other ingredients of Saxenda
- If you are pregnant or you are breastfeeding your baby

Warnings and precautions

Tell your doctor or healthcare professional before using Saxenda if:

- you have severe heart failure, it is not recommended to use Saxenda.
- you have kidney disease or are on dialysis, consult your doctor.
- you have liver problems, consult your doctor.
- you have a severe stomach or gut problem which results in delayed stomach emptying (called gastroparesis), or if you have an inflammatory bowel disease.

People with diabetes

If you have diabetes, do not use Saxenda as a replacement for insulin.

Inflammation of the pancreas

Tell your doctor if you have or have had a disease of the pancreas.

Inflamed gall bladder and gall stones

If you lose substantial weight, you are at a risk of gall stones and thereby inflamed gall bladder. Stop taking Saxenda and consult your doctor immediately if you experience severe pain in your upper abdomen, usually worst on the right side under the ribs. The pain may be felt through to your back or right shoulder.

Thyroid disease

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

Heart rate

Tell your doctor if you have palpitations (you feel aware of your heartbeat) or if you have feelings of a racing heartbeat while at rest during Saxenda treatment.

Loss of fluid and dehydration

With Saxenda, you may have loss of fluids or dehydration. This may be due to feeling sick (nausea), being sick (vomiting) or diarrhoea. It is important to try to stop this dehydration by drinking plenty of fluids. Tell your doctor or your healthcare professional if you have any questions or concerns.

Children and adolescents

Saxenda should not be used in children under 12 years of age or in adolescents with a body weight below or equal to 60 kg. This is because the effects of Saxenda have not been studied in these sub groups.

Using Saxenda with food and drink:

You can inject Saxenda at any time of day, independent of meals.

Other medicines and SAXENDA

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other medicines. This includes medicines obtained without a prescription, and herbal medicines.

In particular, tell your doctor, pharmacist or nurse if:

- You are taking medicines for diabetes called ‘sulphonylurea’ (such as glimepiride or glibenclamide) or if you are taking insulin - you may get low blood sugar (hypoglycaemia) when you use these medicines with Saxenda. Your doctor may adjust the dose of your diabetes medicine to prevent you from getting low blood sugar. See section for the warnings signs of low blood sugar. If you adjust your insulin dose your doctor may recommend you to monitor your blood sugar more frequently.
- You are taking warfarin or other medicines by mouth that reduce your blood clotting (anticoagulants). More frequent blood testing to determine the ability of your blood to clot may be required.

Pregnancy and breast-feeding

- Do not use Saxenda if you are pregnant, think that you might be pregnant or are planning to have a baby. This is because it is not known if Saxenda may affect the baby.

- Do not breast-feed if you are using Saxenda. This is because it is not known if Saxenda passes into breast milk.

Driving and using machines

Saxenda may cause dizziness (*See Possible side effect*) that can impair your ability to drive and use machines. If you need any further information, ask your doctor or healthcare professional.

Important information about some of the ingredients of SAXENDA

Substances added to Saxenda may cause degradation of liraglutide.

In the absence of compatibility studies, Saxenda must not be mixed with other medicines.

3. HOW TO USE SAXENDA

Do not share Saxenda prescribed to you with any other person.

Always use Saxenda exactly as your doctor has instructed you. You should check with your doctor or healthcare professional if you are unsure.

Your doctor will start you on a diet and exercise programme. Stay on this programme while you are using Saxenda.

How much to inject

Your treatment will start at a lower dose which will gradually increase over the first five weeks of treatment.

- When you first start using Saxenda, the starting dose is 0.6 mg once a day, for at least one week.
- You should increase your dose by 0.6 mg each week until you reach the recommended dose of 3.0 mg once a day.

Your doctor will tell you how much Saxenda to use each week.

Usually, you will be told to follow the table below.

Week	**Dose injected**
Week 1	0,6 mg once a day
Week 2	1,2 mg once a day
Week 3	1,8 mg once a day
Week 4	2,4 mg once a day
Week 5 onwards	3,0 mg once a day

Once you reach the recommended dose of 3,0 mg in Week 5 of treatment, keep using this dose until your treatment period ends.

Do not increase your dose further.

You should only continue using Saxenda, if you have lost at least 5 % of your initial body weight after 12 weeks on the 3 mg/day dose.

Consult your doctor before you continue.

Your doctor will assess your treatment on a regular basis.

How and when to use Saxenda

- Before you use the pen for the first time, your doctor or nurse will show you how to use the pen.
- You can use Saxenda at any time of the day, with or without food and drinks.
- Use Saxenda at about the same time each day – find the time of the day that works best for you.

Where to inject

Saxenda is given as an injection under the skin (subcutaneous injection).

- The best places to inject are the front of your waist (abdomen), the front
  of your thighs or your upper arm.
- Change the place within the area where you inject each day to reduce the risk of developing lumps under the skin (see section 4 ‘Possible side effects’).
- Do not inject into a vein or muscle.

Detailed instructions for use are provided at the end of this leaflet.

People with diabetes

Tell your doctor if you have diabetes. Your doctor may adjust the dose of your diabetes medicines to prevent you from getting low blood sugar.

- Do not mix Saxenda up with other medicines that you inject (e.g. insulins).
- Do not use Saxenda in combination with other medicines that contain GLP-1 receptor agonists (such as exenatide, lixisenatide).

If you inject more Saxenda than you should:

If you inject more Saxenda than you should, tell your doctor or go to a hospital straight away. Take the Saxenda pack with you. You may need medical treatment. The following effects may happen:

- Feeling sick (nausea)
- Being sick (vomiting)
- low blood sugar (hypoglycaemia). Please refer to ‘Frequent side effects’ for early warning signs of low blood sugar.

If you forget to inject Saxenda

- If you forget a dose and remember it within 12 hours from when you usually take the dose, inject it as soon as you remember.
- However, if more than 12 hours has passed since you should have used Saxenda, skip the missed dose and inject your next dose the following day at the usual time.
- Do not use a double dose or increase the dose on the following day to make up for the missed dose.

Effects when treatment with Saxenda is stopped:

Do not stop using Saxenda without telling your doctor or healthcare professional.

If you have any further questions on the use of Saxenda ask your doctor or healthcare professional.

4. POSSIBLE SIDE EFFECTS

SAXENDA can have side effects.

Not all side effects reported for SAXENDA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Serious side effects

- Some severe allergic reactions (anaphylaxis) have been reported in patients using Saxenda. You should tell your doctor immediately or go to the casualty department at your nearest hospital if you get symptoms such as breathing problems, swelling of face and throat and a fast heartbeat.
- Cases of inflammation of the pancreas (pancreatitis**)** have been reported in patients using Saxenda. Pancreatitis is a serious, potentially life-threatening medical condition**.**

Stop administering Saxenda and consult your 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 frequent:

- Feeling sick (nausea), being sick (vomiting), diarrhoea, constipation, headache - these usually go away after a few days or weeks

Frequent:

- Problems affecting the stomach and intestines such as: indigestion (dyspepsia), inflammation in the lining of the stomach (gastritis), stomach discomfort, upper stomach pain, heart burn, feeling bloated, wind (flatulence), belching, dry mouth.
- Feeling weak or tired
- Changed sense of taste
- Dizziness
- Difficulty sleeping (insomnia). This usually occurs the first 3 months of treatment
- Gall stones
- Injection site reactions (such as bruising, pain, irritation, itching and rash)

- Low blood sugar (hypoglycaemia).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, being nervous, anxious, confusion, difficulty concentrating and shaking (tremor). Your doctor will tell you how to treat low blood sugar and what to do if you notice these warning signs.

- increase of pancreatic enzymes, such as lipase and amylase

Less frequent:

- Loss of fluids (dehydration).This is more likely to occur at the start of treatment and may be due to being sick (vomiting), feeling sick (nausea) and diarrhoea
- Inflamed gall bladder
- Allergic reactions including skin rash
- Feeling generally unwell
- Faster pulse.
- Reduced kidney function
- Acute kidney failure. Signs may include reduction in urine volume, metallic taste in mouth and easily bruising.

- Lumps under the skin may be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). Saxenda may not work very well if you inject into a lumpy area. Change the injection site with each injection to help prevent this skin change.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of SAXENDA .

5. How to store SAXENDA

Keep Saxenda out of reach of children.

Do not use Saxenda 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 first use:

Store in a refrigerator (2 °C to 8 °C). Do not freeze. Keep away from the freezer compartment.

Once you start using the pen:

You can keep the pen for 1 month when stored at or below 30 °C or in a refrigerator (2 °C to 8 °C). Do not freeze. Keep away from the freezer compartment

When you are not using the pen, keep the pen cap on in order to protect it from light.

Do not use Saxenda if the solution is not clear and colourless.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicines in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What SAXENDA contains

Saxenda contains the active substance liraglutide.

1 millilitre (ml) solution for injection contains 6 milligrams (mg) liraglutide. One pre-filled pen contains 18 mg liraglutide.

The other ingredients are disodium phosphate dihydrate, propylene glycol, phenol and water.

What SAXENDA looks like and contents of the pack

3 ml solution in a cartridge made of colourless type 1 glass with a red rubber plunger (bromobutyl). The cartridge is closed with cream colour rubber stopper (bromobutyl/polyisoprene) and is contained in a pre-filled multidose disposable pen made of polypropylene, polyacetal, polycarbonate and acrylonitrile butadiene styrene.

Each pen is able to deliver doses of 0.6 mg, 1.2 mg,1.8 mg, 2.4 mg and 3.0 mg.

Each pen is designed to be used with NovoFine® or NovoTwist® disposable needles of a length of 4 – 8 mm and a thickness of 30 – 32 G.

The pen(s) is/are packed in hard card board paper

Pack sizes of 1, 3 or 5 pre-filled pens.

Not all pack sizes may be marketed.

Holder of Certificate of Registration

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Access to the corresponding Professional Information

N/A

Instructions for use of prefilled pen

Instructions on how to use Saxenda® 6 mg/ml solution for injection in pre-filled pen

Please read these instructions carefully before using your Saxenda® pre-filled pen.

Do not use the pen without proper training from your doctor; pharmacist or other healthcare professional.

Start by checking your pen to **make sure that it contains Saxenda® 6 mg/ml,** then look at the illustrations below to get to know the different parts of your pen and needle.

If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help.

Get help from a person with good eyesight who is trained to use the Saxenda® pre-filled pen.

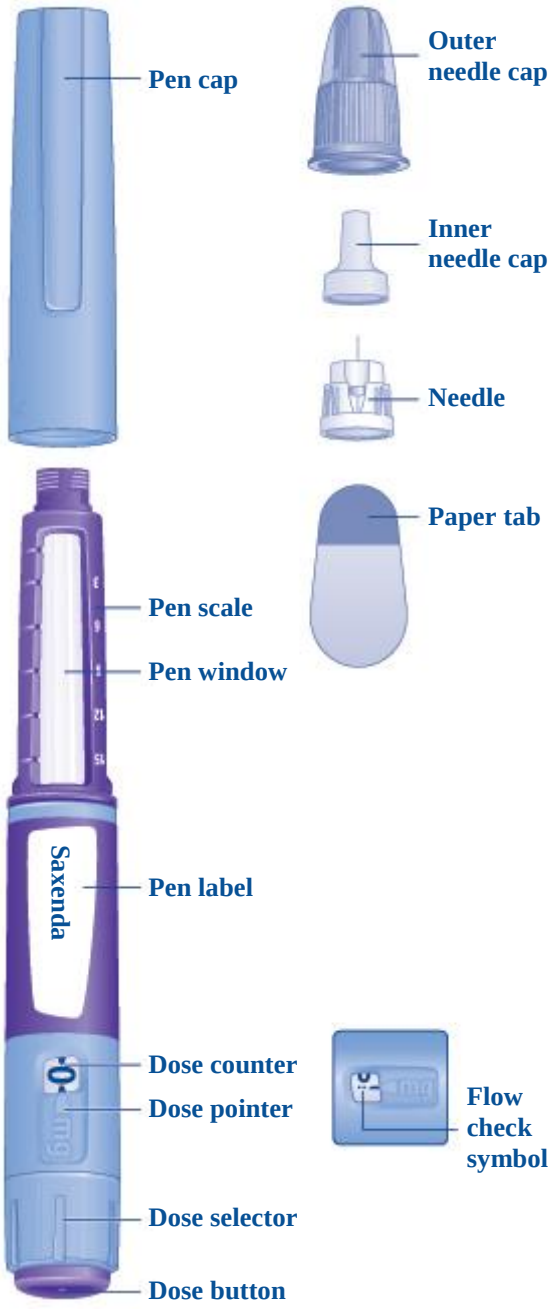
Your pen is a pre-filled dial-a-dose pen. It contains 18 mg of liraglutide, and delivers doses of 0,6 mg, 1,2 mg, 1,8 mg, 2,4 mg and 3,0 mg. Your pen is designed to be used with NovoFine® or NovoTwist® disposable needles of a length of 4 – 8 mm and a thickness of 30 – 32 G.

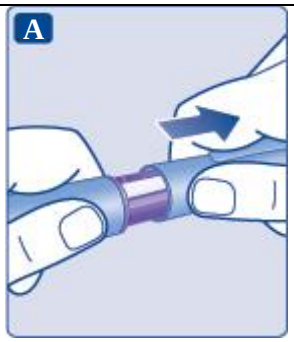
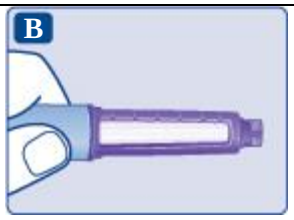
Needles are not included in the pack.

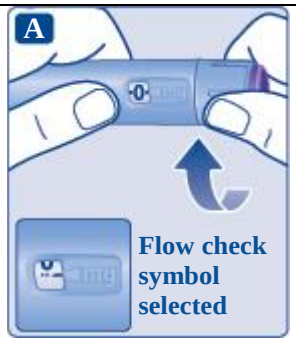
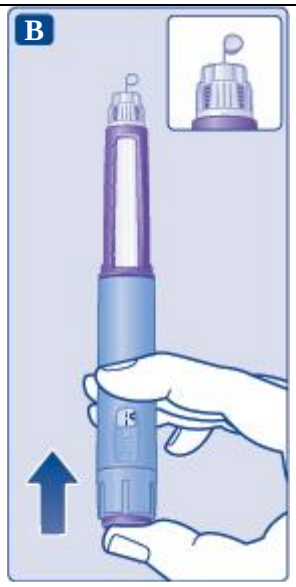
⚠ **Important information**

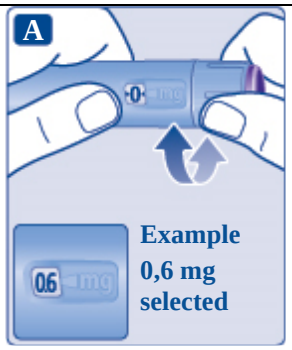
Pay special attention to these notes as they are important for safe use of the pen.

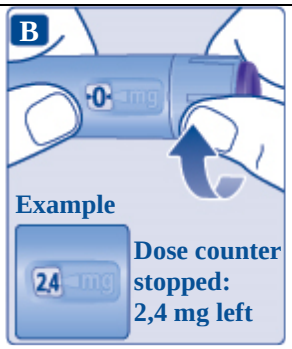
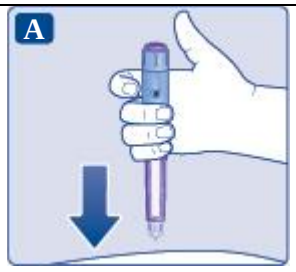
Saxenda pre-filled pen and needle (example)



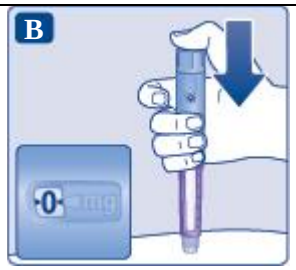
1 Prepare your pen with a new needle • **Check the name and coloured label** of your pen, to make sure that it contains Saxenda®. This is especially important if you take more than one type of injectable medicine. Using the wrong medicine could be harmful to your health. • **Pull off the pen cap.**	
• **Check that the solution in your pen is clear** and colourless. Look through the pen window. If the solution looks cloudy, do not use the pen.	
• **Take a new needle,** and tear off the paper tab.	
Make sure to attach the needle correctly. • Push the needle **straight** onto the pen. • Turn until it is on **tight.**	
The needle is covered by two caps. You must remove both caps. If you forget to remove both caps, you will **not** inject any solution. • **Pull off the outer needle cap and keep it for later.** You will need it after the injection, to safely remove the needle from the pen.	
• **Pull off the inner needle cap and throw it away.** If you try to put it back on, you may accidentally stick yourself with the needle. A drop of solution may appear at the	

needle tip. This is normal, but you must still check the flow, if you use a new pen for the first time. **Do not attach a new needle** to your pen until you are ready to take your injection. ⚠ **Always use a new needle for each injection.** This may prevent blocked needles, contamination, infection and inaccurate dosing. ⚠ **Never use a bent or damaged needle.**	
2 Check the flow with each new pen • If your pen is already in use, go to step 3 ‘Select your dose’. Only check the flow before your **first injection with each new pen.** • Turn the dose selector to **the flow check symbol** (▪▪▬) right past 0. Make sure the flow check symbol lines up with the pointer.	
• Hold the pen with the needle pointing up. **Press and hold in the dose button** until the dose counter returns to 0. The 0 must line up with the dose pointer. A drop of solution should appear at the needle tip. A small drop may remain at the needle tip, but it will not be injected. **If no drop appears,** repeat step 2 ’Check the flow with each new pen’ up to 6 times. If there is still no drop, change the needle and repeat step 2 ’Check the flow with each new pen’ once more. **If a drop still does not appear,** dispose of the pen and use a new one.	

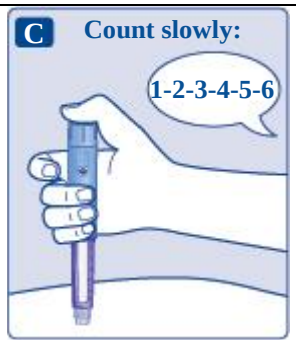
⚠ **Always make sure that a drop appears** at the needle tip before you use a new pen for the first time. This makes sure that the solution flows. If no drop appears, you will **not** inject any medicine, even though the dose counter may move. **This may indicate a blocked or damaged needle.** If you do not check the flow before your first injection with each new pen, you may not get the prescribed dose and the intended effect of Saxenda®.	
3 Select your dose • **Turn the dose selector until the dose counter shows your dose (0,6 mg, 1,2 mg, 1,8 mg, 2,4 mg or 3,0 mg).** If you select the wrong dose, you can turn the dose selector forward or backwards to the correct dose. The pen can dial up to a maximum of 3,0 mg. The dose selector changes the dose. Only the dose counter and dose pointer will show how many mg you select per dose. You can select up to 3,0 mg per dose. When your pen contains less than 3,0 mg the dose counter stops before 3,0 is shown. The dose selector clicks differently when turned forward, backwards or past the number of mg left. Do not count the pen clicks. ⚠ **Always use the dose counter and the dose pointer to see how many mg you have selected before injecting this medicine.** Do not count the pen clicks.	

Do not use the pen scale. It only shows approximately how much solution is left in your pen. **Only doses of 0,6 mg, 1,2 mg, 1,8 mg, 2,4 mg or 3,0 mg must be selected with the dose selector.** The selected dose must line up precisely with the dose pointer to ensure that you get a correct dose.	
How much solution is left? • The **pen scale** shows you **approximately** how much solution is left in your pen.	
• **To see precisely how much solution is left,** use the dose counter: Turn the dose selector until the **dose counter stops.** If it shows 3,0, **at least 3,0 mg** are left in your pen. If the **dose counter stops before 3,0 mg,** there is not enough solution left for a full dose of 3,0 mg. **If you need more medicine than what is left in your pen** Only if trained or advised by your doctor or nurse, you may split your dose between your current pen and a new pen. Use a calculator to plan the doses as instructed by your doctor or nurse. ⚠ **Be very careful to calculate correctly.** If you are not sure how to split your dose using two pens, then select and inject the dose you need with a new pen.	
4 Inject your dose • **Insert the needle into your skin** as your doctor or nurse has shown you. • **Make sure you can see the dose counter.** Do not cover it with your fingers. This could interrupt the injection.	

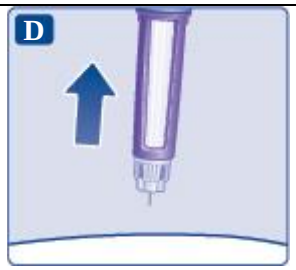
- **Press and hold down the dose button. Watch as the dose counter returns to 0.** The 0 must line up with the dose pointer. You may then hear or feel a click.
- Continue pressing the dose button while keeping the needle in your skin.



- **Count slowly to 6 while keeping the dose button pressed.**
- If the needle is removed earlier, you may see a stream of solution coming from the needle tip. If so, the full dose will not be delivered.



- **Remove the needle from your skin.** You can then release the dose button.



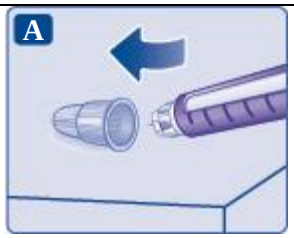
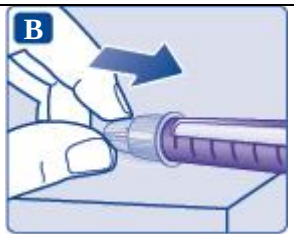
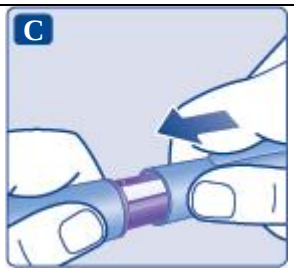
If blood appears at the injection site, press lightly.

You may see a drop of solution at the needle tip after injecting. This is normal and does not affect your dose.

⚠ **Always watch the dose counter to know how many mg you inject**. Hold the dose button down until the dose counter shows 0.

How to identify a blocked or damaged needle?

- If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.
- In this case - you have **not** received **any** medicine - even though the dose counter has

moved from the original dose that you have set. **How to handle a blocked needle?** Change the needle as described in step 5 'After your injection', and repeat all steps starting with step 1 'Prepare your pen with a new needle'. Make sure you select the full dose you need. **Never touch the dose counter when you inject.** This can interrupt the injection.	
5 After your injection • **Always dispose of the needle after each injection** to ensure convenient injections and prevent blocked needles. If the needle is blocked, you will **not** inject any medicine. • **Lead the needle tip into the outer needle cap** on a flat surface without touching the needle or the outer needle cap.	
• Once the needle is covered, **carefully push the outer needle cap completely on.** • **Unscrew the needle** and dispose of it carefully, as instructed by your doctor, nurse, pharmacist or local authorities.	
• **Put the pen cap on** your pen after each use to protect the solution from light. When the pen is empty, throw it away **without** a needle on as instructed by your doctor, nurse, pharmacist or local authorities. ⚠ **Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.**	

⚠ **Always remove the needle from your pen after each injection.** This may prevent blocked needles, contamination, infection, leakage of solution and inaccurate dosing.	
⚠ **Further important information** • Always keep your pen and needles **out of sight and reach of others,** especially children. • **Never share** your pen or your needles with other people. • Caregivers must **be very careful when handling used needles** - to prevent needle injury and cross-infection.	
Caring for your pen • **Do not leave the pen in a car** or other place where it can get too hot or too cold. • **Do not inject Saxenda® which has been frozen.** If you do that, you may not get the intended effect of this medicine. • **Do not expose your pen to dust, dirt or liquid.** • **Do not wash, soak or lubricate your pen.** It may be cleaned with a mild detergent on a moistened cloth. • **Do not drop your pen** or knock it against hard surfaces. If you drop it or suspect a problem, attach a new needle and check the flow before you inject. • **Do not try to refill your pen.** Once empty, it must be disposed of. • **Do not try to repair your pen** or pull it apart.	