PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

This medicine is dispensed with a doctor's prescription only

Saxenda®

Solution for injection in pre-filled pen

Active ingredient: liraglutide 6 mg/ml

Inactive ingredients and allergens in the preparation: see section 2 "Important information about some of this medicine's ingredients" and section 6 "Further information".

Read the entire leaflet carefully before you start using this medicine.

This leaflet contains concise information about the medicine. If you have any further questions ask your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Saxenda is used for weight loss in addition to diet and exercise in adults aged 18 and above who have:

- a BMI of 30 kg/m^2 or greater (obesity) or
- a BMI of 27 to 30 kg/m^2 (overweight) and weight-related health problems (such as diabetes, high blood pressure, abnormal levels of fats in the blood) and who have failed a previous weight management intervention.

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

You should discontinue using Saxenda after 12 weeks of treatment with 3.0 mg/day if you have not lost at least 5% of your initial body weight. Consult your doctor before you continue.

Saxenda can be used in addition to healthy diet and increased physical activity for weight management in adolescents aged 12 years and older with:

- obesity (diagnosed by a doctor)
- body weight above 60 kg

You should only continue using Saxenda if you have lost at least 4% of your BMI after 12 weeks on the 3.0 mg/day dose or maximum tolerated dose (see section 3). Consult your doctor before you continue.

Therapeutic group: Drugs for treatment of diabetes, glucagon-like peptide-1 (GLP-1) analogs.

Saxenda is a weight loss medicine that contains the active substance liraglutide. It is similar to a natural occurring hormone called glucagon-like peptide-1 (GLP-1) that is released from the intestine after a meal. Saxenda works by acting on receptors in the brain that control the appetite, causing you to feel fuller and less hungry. This may help you eat less food and reduce your body weight.

Diet and exercise

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

2. Before using the medicine

Do not use the medicine if:

- you are sensitive (allergic) to liraglutide or any of the other ingredients of this medicine (listed in section 6 "Additional information").

Special warnings about using this medicine

- Talk to your doctor, pharmacist or nurse before using Saxenda.
- The use of this medicine is not recommended if you have severe heart failure.
- There is little experience with this medicine in patients aged 75 years and older. The medicine is not recommended if you are aged 75 or older.
- There is little experience with this medicine in patients with kidney problems. Consult the doctor if you have kidney disease or are on dialysis.
- There is little experience with this medicine in patients with liver problems. Consult the doctor if you have liver problems.
- This medicine is not recommended if 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
Talk to your doctor if you have or have had a disease of the pancreas.

Inflamed gall bladder and gallstones
If you lose substantial weight, you are at a risk of gall stones and thereby inflamed gall bladder. Stop taking Saxenda and contact a doctor immediately if you experience acute 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. See section 4.

Thyroid disease
Consult your doctor if you have thyroid disease including thyroid nodules and enlargement of the thyroid gland.

Heart rate
Talk to 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
When starting treatment with Saxenda, you may lose body fluid or become dehydrated. This may be due to nausea, vomiting and diarrhoea. It is important to avoid dehydration by drinking plenty of fluids. Talk to the doctor, pharmacist or nurse if you have any questions or concerns. See section 4.

Children and adolescents
Saxenda should not be used in children and adolescents under 12 years of age. This is because the effects and safety of this medicine have not been studied in this age group.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular if you are taking:

- medicines for the treatment of diabetes called ‘sulphonylurea’ (such as glimepiride or glibenclamide) or if you are taking insulin - you may get low blood sugar level (hypoglycaemia) when you use these medicines with Saxenda. The doctor may adjust the dose of your diabetes medicine to prevent you from getting low blood sugar level. See section 4 for warning signs of low blood sugar level. If you adjust your insulin dose, the doctor may recommend you to monitor your blood sugar more frequently.
- warfarin or other medicines taken 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 breastfeeding
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 breastfeed if you are using Saxenda. This is because it is not known if Saxenda passes into breast milk.

Driving and using machines
Saxenda is unlikely to affect your ability to drive and use machines.
Some patients may experience dizziness while taking Saxenda, mainly in the first 3 months of treatment (see section "Side effects"). If you experience dizziness, take special care while driving or using machines. Talk to your doctor if you need further information.

Important information about some of this medicine’s ingredients
This medicine contains less than 1 mmol sodium (23 mg) per dose. This means that it is essentially ‘sodium-free’.

3. How to use the medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dosage or about how to take this medicine.

The doctor will start you on a diet and exercise program. Make sure you stay on this program while you are using Saxenda.

The dosage and treatment regimen will be determined by the doctor only. The recommended dosage is usually:

Adults
Your treatment will start at a low dose which will be gradually increased 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.
- Your doctor will instruct you to gradually increase your dose usually by 0.6 mg each week until you reach the recommended dose of 3.0 mg once a day.

The doctor will tell you what dose of Saxenda to use each week. Usually, you will be told to follow the table below.

Week	Dose to be 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.

The doctor will assess your treatment on a regular basis.

Adolescents (≥12 years)
The same schedule of dose elevation used in adults will be implemented for adolescents aged 12 to less than 18 years (see the above table for adults). Increase the dose to 3.0 mg (maintenance dose) or until the maximal tolerated dose is reached. A daily dose exceeding 3.0 mg is not recommended.

Do not exceed the recommended dose.

How and when to use Saxenda
- Before you use the pen for the first time, the doctor or nurse will show you how to use the pen.
- You can use Saxenda at any hour of the day, with or without food and drinks.
- Use Saxenda at about the same hour each day – choose a 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.
- Do not inject into a vein or muscle.

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

People with diabetes
Tell the doctor if you have diabetes. The doctor may adjust the dosage of your diabetes medicines to prevent you from getting low blood sugar level.
- 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 or lixisenatide).

If you have accidentally taken a higher dosage
If you have taken an overdose, or if a child accidentally swallowed the medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you. You may need medical treatment. The following effects may happen:
- nausea
- vomiting
- low blood sugar level (hypoglycaemia). Please see section 4 ("Common side effects") for warning signs of low blood sugar level.

If you forget to use the medicine

- 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 have 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.

Adhere to the treatment as recommended by the doctor.
Do not stop the treatment without consulting your doctor, even if there is an improvement in your health situation.

If you stop taking the medicine
Do not stop taking Saxenda without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose <u>each time</u> you take medicine. Wear glasses if you need them. If you have any further questions on the use of the medicine, ask your doctor or pharmacist.

4. Side effects

As with any medicine, using Saxenda may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

<u>Serious side effects</u>
Some severe allergic reactions (anaphylaxis) have been reported rarely in patients using Saxenda. **You should see your doctor immediately** if you get symptoms such as breathing difficulties, swelling of the face and throat and a fast heartbeat.

Cases of inflammation of the pancreas (pancreatitis) have been reported uncommonly in patients using Saxenda. Pancreatitis is a serious, potentially life-threatening medical condition.
Stop taking Saxenda and contact a doctor immediately if you notice any of the following serious side effects:

- Acute 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).

<u>Additional side effects</u>
Very common: may affect more than 1 in 10 users

- nausea, vomiting, diarrhoea, constipation, headache - these usually go away after a few days or weeks.

Common: may affect up to 1 in 10 users

- problems affecting the stomach and intestines such as indigestion (dyspepsia), inflammation in the lining of the stomach (gastritis), stomach discomfort, upper stomach pain, heartburn, feeling bloated, wind (flatulence), belching and dry mouth
- weakness or tiredness
- changed sense of taste
- dizziness
- difficulty sleeping (insomnia). This usually occurs during the first 3 months of treatment

- gallstones
- injection site reactions (such as bruising, pain, irritation, itching and rash)
- low blood sugar level (hypoglycaemia). The warning signs of low blood sugar level may come on suddenly and can include: cold sweat, cool pale skin, headache, fast heartbeat, nausea, feeling very hungry, changes in vision, sleepiness, weakness, being nervous, anxious, confusion, difficulty concentrating and shaking (tremor). The doctor will tell you how to treat low blood sugar level and what to do if you notice these warning signs.
- increase of pancreatic enzymes, such as lipase and amylase.

Uncommon: may affect up to 1 in 100 users
- loss of fluids (dehydration). This is more likely to occur at the start of treatment and may be due to vomiting, nausea and diarrhoea
- delay in the emptying of the stomach
- inflamed gall bladder
- allergic reactions including skin rash
- feeling generally unwell
- faster pulse.

Rare: may affect up to 1 in 1,000 users
- reduced kidney function
- acute kidney failure. Signs may include reduction in urine volume, metallic taste in mouth and easily bruising.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting of side effects
You can report side effects to the Ministry of Health by following the link "Reporting Side Effects of Drug Treatment" on the Ministry of Health home page (www.health.gov.il) which refers to an online form for reporting side effects. You can also use this link: https://sideeffects.health.gov.il

5. How to store the medicine?

Prevent poisoning! To Prevent poisoning, keep this and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
Do not use the medicine after the expiry date (exp. date) which is stated on the pen label and outer carton. 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 a temperature 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 this medicine if the solution is not clear and colourless, or almost colourless.

Do not throw away any medicine via wastewater or household waste. Ask the

pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

What Saxenda contains
In addition to the active substance, the medicine contains also:
propylene glycol, phenol, disodium phosphate dihydrate, hydrochloric acid and sodium hydroxide and water for injections.

What the medicine looks like and contents of the pack
Saxenda is supplied as a clear, colourless or almost colourless solution for injection in pre-filled pen. One pre-filled pen contains 18 mg liraglutide.
Each pen contains 3 mL solution enabling injection of doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg and 3.0 mg.
Saxenda is available in pack sizes containing 1, 3 or 5 pens. Not all pack sizes may be marketed.
Needles are not included.

Registration holder and address: Novo Nordisk Ltd.,1 Atir Yeda St., Kfar-Saba 4464301.

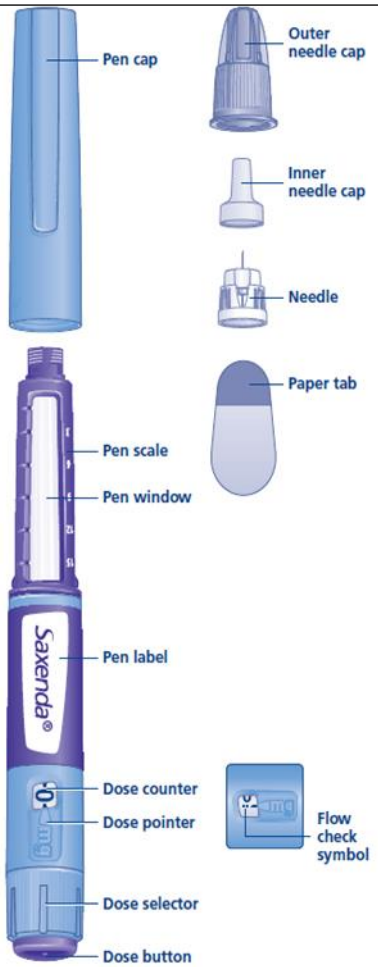
Manufacturer name and address: Novo Nordisk A/S, Novo Allé DK-2880 Bagsværd, Denmark.

Revised in January 2022 according to the MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health: 155-64-34553

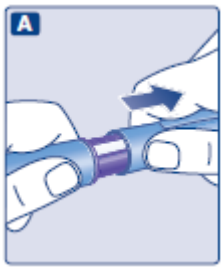
	Instructions on how to use Saxenda 6 mg/ml solution for injection in pre-filled pen **Read the instructions carefully** before using your Saxenda pre-filled pen. **Do not use the pen without proper training** from the doctor or nurse. Start by checking your pen to **make sure that it contains Saxenda 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 enables injection of 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 up to a length of 8 mm and as thin as 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)

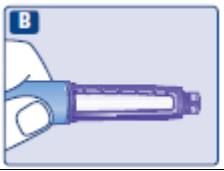


1 Prepare the pen with a new needle

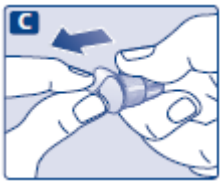
- **Check the name and coloured label** of the pen, to make sure that it contains Saxenda. This is especially important if you take more than one type of injectable medicine. Using the wrong medicine could be harmful to your health.
- **Pull off the pen cap.**



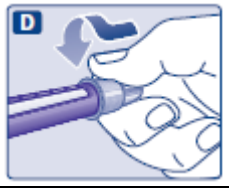
- **Check that the solution in the pen is clear** and colourless. Look through the pen window. Do not use the pen if the solution looks cloudy.

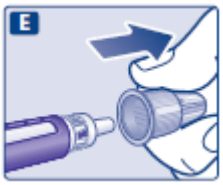
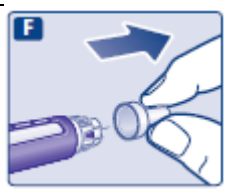
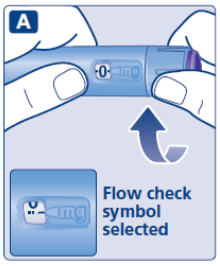
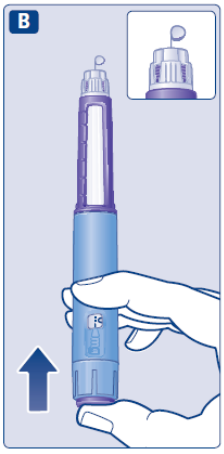


- **Take a new needle** and tear off the paper tab.



- **Push the needle straight onto the pen. Turn until it is on tight.**



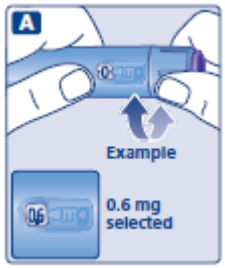
• **Pull off the outer needle cap and keep it for later.** You will need it after the injection, to safely remove the needle from the pen.	
• **Pull off the inner needle cap and throw it away.** If you try to put it back on, you may accidentally stick yourself with the needle. A drop of solution may appear at the needle tip. This is normal, but you must still check the flow of medicine, if you use a new pen for the first time. **Do not attach a new needle** to the pen until you are ready to take your injection. ⚠ **Always use a new needle for each injection.** This may prevent blocked needles, infection transmission, contamination and inaccurate dosing. ⚠ **Never use a bent or damaged needle.**	
2 Check the flow • **Before your first injection with each new pen, check the flow of medicine.** If your pen is already in use, go to step 3 ‘Select your dose’. • Turn the dose selector **until the dose counter shows the flow check symbol ( ).**	
• 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’ up to 6 times. If there is still no drop, change the needle and repeat step 2 ‘Check the flow’ 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 be dialed 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.
  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.



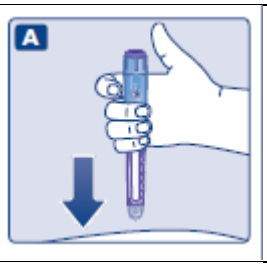
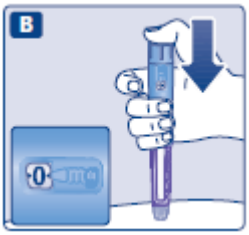
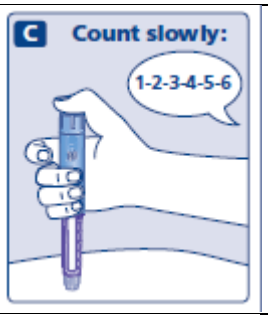
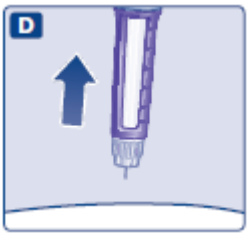
How much solution is left?

- 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 the pen. If the **dose counter stops before 3.0 mg,** there is not enough solution left for a full dose of 3.0 mg.

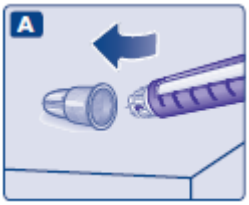
If you need more medicine than what is left in the pen
Only if trained or advised by the doctor or nurse, you may split your dose between the current pen and a new pen. Use a calculator to plan the doses as instructed by the doctor or nurse.

⚠ **Be very careful to calculate correctly.**
If you are not sure how to split your dose using two pens,

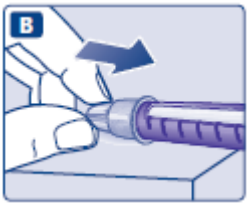
then select and inject the dose you need with a new pen.	
4 Inject your dose • **Insert the needle into your skin** as the doctor or nurse has shown you. • **Make sure you can see the dose counter.** Do not cover it with your fingers. This could interrupt the injection.	
• **Press and hold down the dose button until the dose counter shows 0.** The 0 must line up with the dose pointer. You may then hear or feel a click.	
• **Keep the needle in your skin after** the dose counter has returned to 0 and **count slowly to 6.** • 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.** If blood appears at the injection site, press lightly. Do not rub the area. 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 section 5 ‘After your injection’, and repeat all steps starting with section 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

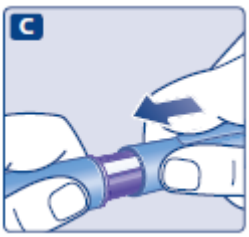
- **Lead the needle tip into the outer needle cap** on a flat surface without touching the needle or the outer needle cap.



- Once the needle is covered, **carefully push the outer needle cap completely on.**
- **Unscrew the needle** and dispose of it carefully



- **Put back the pen cap on** your pen after each use to protect the solution from light
  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.
  When the pen is empty, throw it away **without** a needle on as instructed by the 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 the pen after each injection.**
This may prevent blocked needles, contamination, infection, leakage of solution and inaccurate dosing.

⚠ **Further important information**

- Always keep the 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 the medicine.
- **Do not expose your pen to dust, dirt or liquids.**
- **Do not wash, soak or lubricate your pen.** If necessary, clean it 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.	