Regulatory Operations

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Package leaflet: Information for the patient

Saxenda® 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 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

What Saxenda® is
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 your appetite, causing you to feel fuller and less hungry. This may help you eat less food and reduce your body weight.

What Saxenda® is used 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/m² or greater (obesity) or
- a BMI of 27 kg/m² and less than 30 kg/m² (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 measure of your weight in relation to your height.

You should only continue using Saxenda® if you have lost at least 5% of your initial body weight after 12 weeks on the 3.0 mg/day dose (see section 3). Consult your doctor before you continue.

Saxenda® can be used as an adjunct to a healthy nutrition and increased physical activity for weight management in adolescents from the age of 12 years and above who have:
- obesity (diagnosed by your 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.

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

2. What you need to know before you use Saxenda®

Do not use Saxenda®
- 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 liraglutide.

The use of Saxenda® is not recommended if you have severe heart failure.

There is little experience with this medicine in patients of 75 years and older. It is not recommended if you are 75 years or older.

There is little experience with this medicine in patients with kidney problems. If you have kidney disease or are on dialysis, consult your doctor.

There is little experience with this medicine in patients with liver problems. If you have liver problems, consult your doctor.

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.

If you know that you are due to have surgery where you will be under anaesthesia (sleeping), please tell your doctor that you are taking Saxenda®.

If you have ever had pancreatitis (inflammation of the pancreas) which may cause severe pain in the stomach and back which does not go away; see section 4.

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

Inflamed gall bladder and gallstones
If you lose substantial weight, you are at a risk of gallstones and thereby inflamed gall bladder. Stop taking Saxenda® and contact a 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. See section 4.

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

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 feeling sick (nausea), being sick (vomiting) and diarrhoea. It is important to avoid dehydration by drinking plenty of fluids. Talk to your doctor, pharmacist or nurse if you have any questions or concerns. See section 4.

Children and adolescents
The safety and efficacy of Saxenda® in children below 12 years of age has not been studied.

Other medicines and Saxenda®
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 taking medicines for diabetes called 'sulfonylurea' (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 4 for the warning 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® is unlikely to affect your ability to drive and use machines.
Some patients may feel dizziness when taking Saxenda® mainly during the first 3 months of treatment (see section **'Possible side effects'**). If you feel dizziness be extra careful while driving or using machines. If you need any further information, talk to your doctor.

Important information about some of the ingredients of Saxenda®
This medicine contains less than 1 mmol sodium (23 mg) per dose, i.e. essentially 'sodium-free'.

3. How to use Saxenda®

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

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

How much to inject

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 by 0.6 mg usually 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.

Your doctor will assess your treatment on a regular basis.

Adolescents (≥ 12 years)
For adolescents from the age of 12 to below 18 years old a similar dose escalation schedule as for adults should be applied (see above table for adults). The dose should be increased until 3.0 mg (maintenance dose) or maximum tolerated dose has been reached. Daily doses higher than 3.0 mg are not recommended.

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 drink.
- Use Saxenda® at about the same time 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.
- Change the place where you inject each day to reduce the risk of developing lumps.
- Do not inject into a vein or muscle.

Detailed instructions for use are provided on the other side 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 or lixisenatide).

If you use more Saxenda® than you should
If you use more Saxenda® than you should, talk to a doctor or go to a hospital straight away. Take the medicine 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 'Common side effects' for warning signs of low blood sugar.

If you forget to use Saxenda®
- If you forget a dose and remember it within 12 hours from when you usually use 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.

If you stop using Saxenda®
Do not stop using Saxenda® without talking to your doctor.

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
Some severe allergic reactions (anaphylaxis) have been reported rarely in patients using Saxenda®. You should see your doctor straight away if you get symptoms such as breathing problems, swelling of face and throat and a fast heartbeat.
- Inflamed pancreas (acute pancreatitis), which could cause severe pain in the stomach and back which does not go away. Cases of pancreatitis have been reported uncommonly in patients using Saxenda. This is a serious, potentially life-threatening condition. You should see a doctor immediately if you experience such symptoms
- Stop taking Saxenda 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, with or without nausea and vomiting. This could be a sign of acute pancreatitis which is serious and potentially life-threatening.

Other side effects
Very common: may affect more than 1 in 10 people
- Feeling sick (nausea), being sick (vomiting), diarrhoea, constipation, headache – these usually go away after a few days or weeks.

Common: may affect up to 1 in 10 people
- 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
- Feeling weak or tired
- Changed sense of taste
- Dizziness
- Difficulty sleeping (insomnia). This usually occurs during the first 3 months of treatment
- Gallstones
- Rash
- 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, being 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.

Uncommon: may affect up to 1 in 100 people
- 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
- 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 people
- Reduced kidney function
- Acute kidney failure. Signs may include reduction in urine volume, metallic taste in mouth and easily bruising.

Not Known: frequency cannot be estimated from the available data
- Bowel obstruction. A severe form of constipation with additional symptoms such as stomach ache, bloating, vomiting etc.
- 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 Yellow Card Scheme
Website: https://yellowcard.mhra.gov.uk/ or search for MHRA Yellow Card in the Google Play or Apple App Store

By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Saxenda®

Keep this medicine out of the sight and 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 - 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 - 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 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 Saxenda® 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, phenol, hydrochloric acid and sodium hydroxide (for pH adjustment) and water for injections.

What Saxenda® looks like and contents of the pack
Saxenda® is supplied as a clear and colourless or almost colourless solution for injection in a pre-filled pen. Each pen contains 3 ml solution and is able to deliver 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.

Marketing Authorisation Holder and Manufacturer
Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

This leaflet was last revised in 08/2025

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Length: Max. 20 mm (100%)
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Saxenda®
6 mg/ml
Solution for injection in pre-filled pen
liraglutide

novo nordisk®

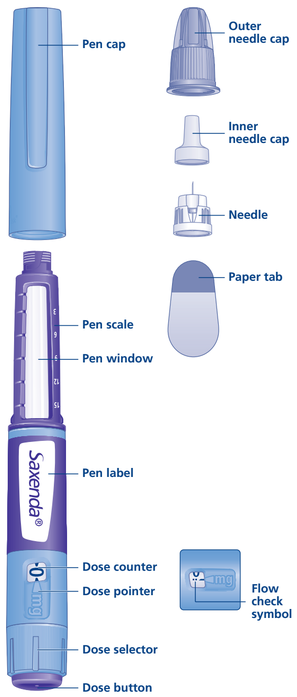
8 mm
1 mm

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 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 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 up to a length of 8 mm and as thin as 32 G.
Needles are not included in the pack.

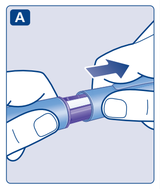
⚠ **Important information**
Pay special attention to these notes as they are important for safe use of the pen.

Saxenda® pre-filled pen and needle (example)

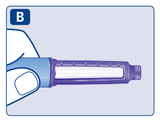


1 Prepare your pen with a new needle

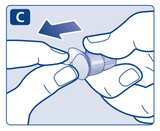
- **Check the name and coloured label** of your pen, to make sure that it contains Saxenda®. This is especially important if you take more than one type of injectable medicine. Using the wrong medicine could be harmful to your health.
- **Pull off the pen cap.**



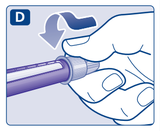
- **Check that the solution in your pen is clear** and colourless. Look through the pen window. If the solution looks cloudy, do not use the pen.



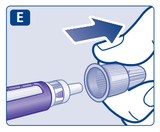
- **Take a new needle** and tear off the paper tab.



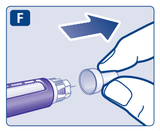
- **Make sure to attach the needle correctly.**
- **Push the needle straight onto the pen.**
- **Turn until it is on tight.**



- **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.



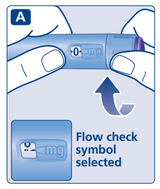
- **Pull off the inner needle cap and throw it away.** If you try to put it back on, you may accidentally stick yourself with the needle. A drop of solution may appear at the needle tip. This is normal, but you must still check the flow if you use a new pen for the first time.
Do not attach a new needle to your pen until you are ready to take your injection.



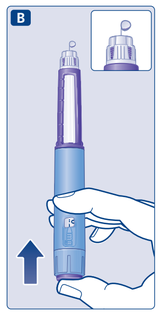
⚠ **Always use a new needle for each injection.**
This may prevent blocked needles, contamination, infection and inaccurate dosing.
⚠ **Never use a bent or damaged needle.**

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.

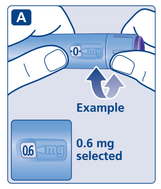


A small drop may remain at the needle tip, but it will not be injected.
If no drop appears, repeat step 2 'Check the flow with each new pen' up to 6 times. If there is still no drop, change the needle and repeat step 2 'Check the flow with each new pen' once more.
If a drop still does not appear, dispose 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.

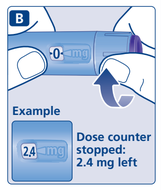
⚠ **Always use the dose counter and the dose pointer to see how many mg you have selected before injecting this medicine.**
Do not count the pen clicks.
Do not use the pen scale. It only shows approximately how much solution is left in your pen.
Only doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3.0 mg 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.

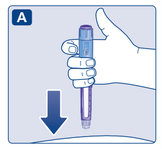


If you need more medicine than what is left in your pen
Only if trained or advised by your doctor or nurse, you may split your dose between your current pen and a new pen. Use a calculator to plan the doses as instructed by your doctor or nurse.

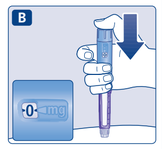
⚠ **Be very careful to calculate correctly.**
If you are not sure how to split your dose using two pens, then select and inject the dose you need with a new pen.

4 Inject your dose

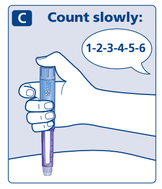
- **Insert the needle into your skin** as your doctor or nurse has shown you.
- **Make sure you can see the dose counter.** Do not cover it with your fingers. This could interrupt the injection.



- **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.



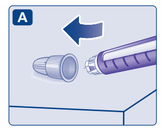
You may see a drop of solution at the needle tip after injecting. This is normal and does not affect your dose.

⚠ **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.

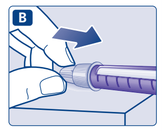
How to handle a blocked needle?
Change the needle as described in step 5 'After your injection' and repeat all steps starting with step 1 'Prepare your pen with a new needle'. Make sure you select the full dose you need.
Never touch the dose counter when you inject.
This can interrupt the injection.

5 After your injection

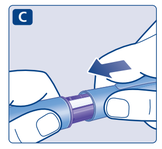
- **Always dispose of the needle after each injection to ensure convenient** injection and prevent blocked needles. If the needle is blocked, you will **not** inject any medicine.
- **Lead the needle tip into the outer needle cap** on a flat surface without touching the needle or the outer needle cap.



- 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.
- Change the place where you inject each day to reduce the risk of developing lumps.

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.

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