Package leaflet: information for the user

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

Read the entire 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.
- Do you have any questions? Contact your doctor, pharmacist, or nurse.
- Do not pass this medicine on to others, as it has been prescribed for you only. It may harm them, even if their symptoms are the same as yours.
- Do you experience any side effects listed in section 4? Or do you experience a side effect not listed in this leaflet? Contact your doctor, pharmacist, or nurse.

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1. What is Saxenda and what is it used for?

What is Saxenda?
Saxenda is a weight loss medicine that contains the active substance liraglutide. It is similar to a naturally occurring hormone called glucagon-like peptide-1 (GLP-1) that is released from the intestines after a meal. Saxenda acts on receptors in the brain that regulate your appetite and makes you feel full and less hungry. This can help you eat less and reduce your body weight.

What is this medicine used for?
Saxenda is used for weight loss as an adjunct to a diet and exercise in adults aged 18 years and older with:
- a BMI of 30 kg/m² or higher (obesity) or
- a BMI between 27 kg/m² and 30 kg/m² (overweight) with weight-related health problems (such as diabetes, high blood pressure, abnormal blood lipid levels, or breathing difficulties during sleep, also known as 'obstructive sleep apnea').

BMI (Body Mass Index) is an index for weight in relation to body height.

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

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

- obesity (determined 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 of using the 3.0 mg/day dose or the maximum tolerable dose (see section 3). Consult your doctor before continuing.

Saxenda can be used as an addition to healthy eating and increased physical activity for weight management in children aged 6 to < 12 years with:
obesity (determined by your doctor)
body weight of 45 kg or higher.

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

Diet and exercise
Your doctor will prescribe you a diet and exercise program. Stick to this program while using Saxenda.

2. When should you not use this medicine or be extra careful with it?

When should you not use this medicine?
- You are allergic to any of the ingredients in this medicine. You can find these ingredients in section 6.

When should you be extra careful with this medicine?
Contact your doctor, pharmacist, or nurse before using this medicine.

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

There is little to no experience with this medicine in patients aged 75 years and older. It is not recommended if you are 75 years or older.

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

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

This medicine is not recommended if you have chronic inflammatory bowel disease (IBD) or if you have a severe stomach or intestinal problem that leads to delayed stomach emptying (this is called gastroparesis).

If you know you are going to have surgery where you will be under anesthesia (asleep), tell your doctor that you are using Saxenda.

Diabetes

If you have diabetes, you should not use Saxenda as a substitute for insulin.

Inflammation of the pancreas

Consult your doctor if you have or have had a condition of the pancreas.

Inflamed gallbladder and gallstones

If you lose a lot of weight, you may develop gallstones and consequently an inflamed gallbladder. Stop using Saxenda and consult a doctor immediately if you notice severe pain in your upper abdomen, usually worst on the right side under the ribs. The pain may radiate to your back or right shoulder. See section 4.

Thyroid disorder

If you have a thyroid disorder, such as thyroid nodules and an enlargement of the thyroid gland, consult your doctor.

Heart rate

Contact your doctor if you experience palpitations (you feel your own heartbeat) or a feeling of a racing heart at rest during treatment with Saxenda.

Fluid loss and dehydration

When you start treatment with Saxenda, you may experience fluid loss or dehydration. This can occur if you are nauseous, vomiting, or have diarrhea. It is important to prevent dehydration by drinking enough fluids. Contact your doctor, pharmacist, or nurse if you have questions or concerns. See section 4.

Children
The safety and efficacy of Saxenda in children under 6 years have not been established.

Are you taking any other medicines?
Are you using any other medicines alongside Saxenda, have you done so recently, or is there a possibility that you will use other medicines soon? Then tell your doctor, pharmacist, or nurse.

Especially contact your doctor, pharmacist, or nurse in the following cases:

- If you are using diabetes medicines called 'sulfonylureas' (such as glimepiride or glibenclamide) or if you are using insulin – you may get low blood sugar (hypoglycemia) if 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 that you check your blood sugar more often.
- If you are using warfarin or other oral medicines that reduce your blood clotting (anticoagulants). Blood tests to test your blood's clotting ability may be necessary more often.

Pregnancy and breastfeeding
Are you pregnant, do you think you might be pregnant, do you want to become pregnant, or are you breastfeeding? Then contact your doctor or pharmacist before using this medicine.

Do not use Saxenda if you are pregnant, think you might be pregnant, or want to become pregnant. It is not known whether Saxenda affects the baby.

Do not use Saxenda if you are breastfeeding. It is not known whether Saxenda is excreted in breast milk.

Driving and using machines
Saxenda is unlikely to affect your ability to drive and use machines.
Some patients may feel dizzy, mainly during the first 3 months of treatment with Saxenda (see section 'Possible side effects'). If you feel dizzy, be extra careful when driving and using machines. For more information, contact your doctor.
Important information about some of the ingredients in Saxenda
This medicine contains less than 1 mmol sodium (23 mg) per dose, which means it is essentially 'sodium-free'.

3. How to use this medicine?

Always use this medicine exactly as your doctor has told you. Are you unsure about the correct use? Then contact your doctor, pharmacist, or nurse.

Your doctor will prescribe a diet and exercise program for you. Stick to this program while using Saxenda.

How much to inject

Adults
Your treatment will start with a low dose that is gradually increased over the first five weeks of treatment.

- When you start using Saxenda, the starting dose is 0.6 mg once a day, for at least one week.
- Your doctor will give you instructions to gradually increase your dose by 0.6 mg. This usually happens weekly until you reach the recommended dose of 3.0 mg once a day.

Your doctor will tell you how much Saxenda you should use each week. Usually, you will need to follow the table below.

Week	Injected dose
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 and onwards	3.0 mg once a day

Once you use the recommended dose of 3.0 mg in week 5 of treatment, you will continue to use this dose until the end of your treatment period. Do not increase the dose further.

Your doctor will regularly monitor your treatment.

Children and adolescents (6 to 18 years)

For children and adolescents aged 6 to 18 years, a similar dose escalation schedule should be applied as for adults (see the table above for adults). The dose should be increased to 3.0 mg (maintenance dose) or until the maximum tolerable dose is reached. Doses higher than 3.0 mg per day are not recommended.

How and when to use this medicine?

Before using the pen for the first time, have your doctor or nurse 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 every day at approximately the same time. Choose a time that suits you best.

Where to inject?

Saxenda is administered by injection under the skin (subcutaneous injection).

The best places to inject are the front of your abdomen, the front of your thighs, or your upper arms.
Change the injection site every day to reduce the risk of developing lumps.
Do not inject into a vein or muscle.

You will find detailed instructions for use on the reverse side of this leaflet.

Diabetes

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

Do not mix Saxenda with other injectable medications (such as insulins).
Do not use Saxenda in combination with other medications that contain GLP-1 receptor agonists (such as exenatide or lixisenatide).

Have you used too much of this medicine?

Contact your doctor immediately or go to a hospital right away if you have used more Saxenda than you should. Take the medicine box with you. You may need medical treatment.
The following side effects may occur:

nausea
vomiting
low blood sugar (hypoglycemia). See the warning signs of low blood sugar under 'Other side effects; common'.

Have you forgotten to use this medicine?

If you miss a dose and remember within 12 hours of the usual time of use, inject the medicine as soon as you remember.
However, if it has been more than 12 hours since you should have used Saxenda, skip the missed dose and inject the next dose the next day at the usual time.
Do not take a double dose the next day to make up for the missed dose. Also, do not increase the dose the next day to make up for a missed dose.

If you stop using this medicine

Do not stop using Saxenda without consulting your doctor.

Do you have any other questions about the use of this medicine? Then contact 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 serious allergic reactions (anaphylaxis) have been rarely reported in patients treated with Saxenda. You should contact your doctor immediately if you have symptoms such as difficulty breathing, swelling of the face and throat, and a rapid heartbeat.

Cases of inflammation of the pancreas (pancreatitis) have been rarely reported in patients treated with Saxenda. Pancreatitis is a serious, potentially life-threatening condition. Stop using 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 may radiate to your back, as well as nausea and vomiting, as these may be signs of an inflamed pancreas (pancreatitis).

Other side effects

Very common: affects more than 1 in 10 users

- Nausea, vomiting, diarrhea, constipation, headache – these usually go away after a few days or weeks.

Common: affects less than 1 in 10 users

- Stomach and intestinal problems, such as indigestion (dyspepsia), inflammation of the stomach lining (gastritis), stomach discomfort, upper abdominal pain, heartburn, bloating, flatulence, belching, and dry mouth.
- Feeling weak or tired.
- Altered sense of taste.
- Dizziness.
- Insomnia. This side effect usually occurs during the first 3 months of treatment.
- Gallstones.
- Skin rash.
- Injection site reactions (such as bruising, pain, irritation, itching, and rash).
- Low blood sugar (hypoglycemia). The warning signs of low blood sugar can come on suddenly and include: cold sweat, cool pale skin, headache, rapid heartbeat, nausea, feeling very hungry, changes in vision, feeling drowsy, feeling weak, nervous, anxious, confused, having difficulty concentrating, shaking (tremor). Your doctor will tell you how to treat low blood sugar and what to do if you experience these warning signs.
- Increase in pancreatic enzymes, such as lipase and amylase.

Sometimes: occur in less than 1 in 100 users

- Fluid loss (dehydration). This usually occurs at the start of treatment and can result from nausea, vomiting, and diarrhea.
- Delayed gastric emptying.
- Inflammation of the gallbladder.
- Allergic reactions including skin rash.

General feeling of being unwell.
Faster pulse.

Rarely: occur in less than 1 in 1,000 users
Reduced kidney function.
Acute kidney failure. Symptoms include reduced urine volume, metallic taste in the mouth, and rapid onset of bruising.

Not known (cannot be determined from the available data)
Intestinal obstruction. A severe form of obstruction with symptoms such as abdominal pain, bloating, vomiting, etc.
Lumps under the skin can be caused by the accumulation of a protein called amyloid (skin amyloidosis; how often this occurs is not known).

Reporting side effects
If you experience side effects, contact your doctor, pharmacist, or nurse. This also applies to any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system as listed in Appendix V. By reporting side effects, you can help us obtain more information about the safety of this medicine.

5. How to store this medicine?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date. You can find this on the label of the pen and on the carton after EXP. It includes a month and a year. The last day of that month is the expiry date.

Before first use:

Store in a refrigerator (2°C-8°C). Do not freeze. Do not store near the freezer compartment.

After first use of the pen:

If you store the pen below 30°C or in the refrigerator (2°C-8°C), you can keep the pen for one month. Do not freeze. Do not store near the freezer compartment.

Store the pen with the cap on when not in use to protect it from light.

Do not use this medicine if the solution is not clear and colorless or almost colorless.

Do not dispose of medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer use. Proper disposal helps ensure they are destroyed responsibly and do not enter the environment.

6. Contents of the pack and other information

What does this medicine contain?

- The active substance in this medicine is liraglutide. 1 ml solution for injection contains 6 mg liraglutide. A pre-filled pen contains 18 mg liraglutide.
- The other ingredients in this medicine are disodium phosphate dihydrate, propylene glycol, phenol, hydrochloric acid, and sodium hydroxide (for pH adjustment) and water for injections.

What does Saxenda look like and what is in a pack?
Saxenda is provided as a clear and colorless or almost colorless solution for injection in a pre-filled pen. Each pen contains 3 ml of solution for the administration of doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, and 3.0 mg.

Saxenda is available in packages of 1, 3, or 5 pens. Not all mentioned package sizes are marketed.

Needles are not included.

Marketing authorization holder
Novo Nordisk A/S
Novo Alle 1
DK-2880 Bagsværd
Denmark

Manufacturer
Novo Nordisk A/S
Novo Alle 1
DK-2880 Bagsværd
Denmark

Novo Nordisk Production SAS
45 Avenue D Orleans
28000 Chartres
France

This leaflet was last approved in

Other sources of information

More information about this medicine is available on the website of the European Medicines Agency: http://www.ema.europa.eu.

Instructions for use of Saxenda 6 mg/ml solution for injection in pre-filled pen

Read these instructions carefully before using your pre-filled pen with Saxenda.
Do not use the pen without proper training by your doctor or nurse.
Start by checking the pen; ensure that the pen contains Saxenda 6 mg/ml. Then refer to the images below to familiarize yourself with the different parts of your pen and needle.
If you are blind or have poor eyesight and cannot read the dose display window on the pen, do not use this pen without assistance. Seek help from a person with good vision who is trained in using the Saxenda pre-filled pen.
Your pen is a pre-filled pen with a dialable dose selector. The pen contains 18 mg 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 for use with NovoFine or NovoTwist single-use needles with a maximum length of 8 mm and a thickness of 32 G.
Needles are not included in the package.

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

1 Attaching a new needle to your pen

Check the name and colored label on your pen to ensure it contains Saxenda. This is especially important if you use more than one type of injectable medicine. Using the wrong medicine can be harmful to your health.
Remove the pen cap from the pen.
Check that the solution in the pen is clear and colorless. Look through the pen window.
If the solution appears cloudy, do not use the pen.
Take a new needle and remove the paper tab.

Ensure that you attach the needle correctly.
Press the needle straight onto the pen.
Screw the needle on tightly.

There is a needle cap and needle cover on the needle. You must remove both. If you do not remove both, you will not inject any solution.

Remove the outer needle cap and keep it for later. You will need it after the injection to safely remove the needle from the pen.

Remove the inner needle cap and discard it. If you try to put it back, you might accidentally prick yourself with the needle.
A drop of solution may appear at the needle tip. This is normal, but you should still check the flow if you are using a new pen for the first time. Only attach a new needle to the pen when you are ready to administer the injection.

Always use a new needle for each injection.
This helps prevent needle blockage, contamination, infection, and incorrect dosage.
Never use a bent or damaged needle.

2 Check the flow with each new pen

If your pen is already in use, proceed to step 3 'Setting your dose'. Check the flow only before your first injection with each new pen.
Turn the dose selector to the flow check line (** =) directly after 0. Ensure the flow check line is aligned with the dose pointer.
Hold the pen with the needle pointing upwards.
Press the dose button and hold it until the dose display returns to 0. The number 0 should be opposite the dose pointer.
A drop of solution should now 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 'Checking the flow with each new pen' up to 6 times. If still no drop appears, change the needle and repeat step 2 'Checking the flow with each new pen' once more.
If still no drop appears, discard the pen and use a new one.

Always check for a drop at the needle tip before using a new pen for the first time. This ensures that the solution is flowing.
If no drop appears, no medication will be injected, even if the number in the dose display changes. The absence of a drop 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 receive the prescribed dose and Saxenda may not work as intended.

3 Setting your dose

Turn the dose selector until your dose appears in the dose display window (0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, or 3.0 mg).
If you set the wrong dose, you can turn the dose selector forward or backward to set the correct dose.
You can set a maximum of 3.0 mg with the pen.

The dose selector changes the dose. Only the dose display window and the dose pointer indicate how many mg you set per dose.
You can set a maximum of 3.0 mg per dose. Once the pen contains less than 3.0 mg, the dose display window stops before displaying 3.0.
The dose selector makes a different clicking sound when turned forward, backward, or past the number of remaining mg. Do not count the number of clicks of the pen.

Always use the dose display window and the dose pointer to see how many mg you have set before injecting this medicine.
Do not count the number of clicks of the pen.
Do not use the scale on the pen. It only indicates approximately how much solution is left in the pen.
With the dose selector, you can only set doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg, or 3.0 mg. The number of the set dose must be exactly opposite the dose pointer to ensure you get a correct dose.

How much solution is left?

The scale indicates approximately how much solution is left in the pen.

If you want to see exactly how much solution is left in the pen, use the dose display window:
Turn the dose selector until the dose display window stops.
If 3.0 is displayed, there is at least 3.0 mg left in the pen. If the dose display window stops before 3.0 mg is displayed, there is not enough solution left for a full dose of 3.0 mg.

If you need more medicine than is left in your pen
Only if it has been explained or advised by your doctor or nurse, you may split your dose between your current pen and a new pen. Use a calculator to calculate the doses according to the instructions of your doctor or nurse.

Make sure to calculate carefully.
If you are unsure how to split your dose between two pens, use a new pen to set and inject the required dose.

4 Inject the dose

Insert the needle into the skin in the way your doctor or nurse has shown you.
Make sure you can see the dose display window. Do not cover the dose display window with your fingers, as this may interrupt the injection.

Press the push button and hold it down. Watch the dose display window return to 0. The number 0 should be opposite the dose pointer arrow. You may hear or feel a click. Keep pressing the push button while holding the needle in your skin.

Count slowly to 6 while holding the push button down.
If the needle is removed earlier, you may see a stream of solution coming from the needle tip. In that case, the full dose is not administered.

Remove the needle from your skin. You can then release the push button.

If the injection site starts to bleed, press gently against it.

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

Always keep looking at the dose display window so you know how many mg you are injecting. Keep the push button pressed until the dose display window shows 0. How do you recognize a blocked or damaged needle?
If, after repeatedly pressing the push button, the dose display window does not show 0, you may have used a blocked or damaged needle.
In that case, you have not received any medication, even if the number in the dose display window has changed from the set dose.

What should you do with a blocked needle?
Replace the needle as described in step 5 'After your injection' and repeat all steps from step 1 'Preparing your pen with a new needle'. Set the full required dose.

Do not touch the dose display window during injection. This may interrupt the injection.

5 After your injection

To prevent a blocked needle and ensure a successful injection, you must always unscrew and remove the needle after each injection. If the needle is blocked, no medication is injected.
Place the outer needle cap on a flat surface and insert the needle tip into it, without touching either.

Press the outer needle cap on carefully and completely when the needle is covered. Unscrew the needle and dispose of it carefully as instructed by your doctor, nurse, pharmacist, or local authorities.

Replace the pen cap on your pen after each use to protect the solution from light.

When the pen is empty, dispose of it without a needle attached, as prescribed by your doctor, nurse, pharmacist, or local authorities.

Never attempt to replace the inner needle cap on the needle. You could prick yourself with the needle.
Always remove the needle from your pen after each injection.
This prevents the needle from becoming clogged, contamination, infection, solution leakage, and incorrect dosing.

Other important information
Always keep your pen and needles out of sight and reach of others, especially children.
Never share your pen or needles with other people.
Caregivers must be very careful when handling used needles to prevent needle stick injuries and cross-contamination.
Rotate the injection site daily to reduce the risk of lump formation.

Caring for your pen

Do not leave the pen in a car or any place where it can become too hot or too cold.
Saxenda that has been frozen should not be injected. If you use Saxenda that has been frozen, this medicine may not work as intended.
Do not expose your pen to dust, dirt, or liquid.
Do not wash, immerse, or lubricate your pen. It can be cleaned with a mild detergent on a damp cloth.
Do not drop your pen or knock it against a hard surface. If you drop the pen or suspect a problem, you should attach a new needle and check the flow before injecting.
Do not attempt to refill your pen. If the pen is empty, it must be discarded.
Do not attempt to repair or disassemble your pen.