Package leaflet: Information for the patient

Saxenda® 6 mg/ml
Solution for injection in pre-filled pen
Liraglutide

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

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

What Saxenda® is
Saxenda® is a weight loss medicine that contains the active substance liraglutide. It is similar to a natural occurring hormone called 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 or greater (obese) or
- a 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 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 mg/day 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 Saxenda®.

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.

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 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
Saxenda® should not be used in children and adolescents under 18 years of age. This is because the effects of this medicine have not been studied in this age group.

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) – 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 warnings signs of low blood sugar.
- 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. If you need any further information, talk to your doctor, pharmacist or nurse.

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

3. How to use Saxenda®

Always use Saxenda® 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
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.
- 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.

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 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.
- 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).

If you forget to use 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 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.

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

Other side effects
Very common: may affect more than 1 in 10 people
- Feeling sick (nausea), being sick (vomiting), diarrhoea, constipation – 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 the first 3 months of treatment
- Gallstones
- 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
- 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.

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

United Kingdom:
Yellow Card Scheme
Website: www.mhra.gov.uk/yellowcard

Ireland:
HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2, Tel: +353 1 6764971,
Fax: +353 6762517, Website:www.hpra.ie, e-mail: medsafety@hpra.ie

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 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 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
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Novo Allé
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