Saxenda®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Saxenda®?

Saxenda® contains the active ingredient liraglutide. Saxenda® is used in weight loss, in addition to diet and exercise in adults aged 18 years or older.
For more information, see Section 1. Why am I using Saxenda®? in the full CMI.

2. What should I know before I use Saxenda®?

Do not use if you have ever had an allergic reaction to liraglutide or any of the ingredients listed at the end of the CMI.
Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.
For more information, see Section 2. What should I know before I use Saxenda®? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Saxenda® and affect how it works.
A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Saxenda®?

- Your doctor or pharmacist will have given you advice on how to use your medicine.
- The usual starting dose of Saxenda® is 0.6 mg once per day, which will be increased step wise until reaching the recommended dose of 3.0 mg once a day.

More instructions can be found in Section 4. How do I use Saxenda®? in the full CMI.

5. What should I know while using Saxenda®?

Things you should do	• Remind any doctor, dentist or pharmacist or health professional you visit that you are using Saxenda®. • Tell your doctor if you have diabetes, or a racing heartbeat when at rest.

	• Do not use Saxenda® in combination with other medicines that contain GLP-1 receptor agonists.
Things you should not do	• Do not stop using this medicine unless your doctor tells you to.
Driving or using machines	• Be careful driving or operating machinery until you know how Saxenda® affects you.
Drinking alcohol	• n/a
Looking after your medicine	• Before opening, store Saxenda® pens in a refrigerator (2°C to 8°C). Do not freeze. • During use, Saxenda® pens can be stored for 1 month either at room temperature (below 30°C) or in a refrigerator (2°C to 8°C). Store the pen without a needle attached.

For more information, see Section 5. What should I know while using Saxenda®? in the full CMI.

6. Are there any side effects?

The most common side effects are feeling sick (nausea), being sick (vomiting), diarrhoea, constipation, headache, changed sense of taste, dizziness, indigestion (dyspepsia), feeling bloated, burping, wind (flatulence) or dry mouth, heartburn, painful or swollen abdomen, low blood sugar (a hypo), injection site reactions, fast heartbeat, feeling weak or tired, difficulty sleeping (insomnia), increase of pancreatic enzymes and rash. More serious side effects include severe and persistent pain in the abdomen, lump or swelling in the neck, hoarseness, trouble swallowing or shortness of breath, signs of reduced kidney function, signs of gallbladder problems, depression and bowel obstruction.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Saxenda®

Active ingredient(s): *Liraglutide*

Consumer Medicine Information (CMI)

This leaflet provides important information about using Saxenda®. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Saxenda®.**

Where to find information in this leaflet:

1. Why am I using Saxenda®?
2. What should I know before I use Saxenda®?
3. What if I am taking other medicines?
4. How do I use Saxenda®?
5. What should I know while using Saxenda®?
6. Are there any side effects?
7. Product details

1. Why am I using Saxenda®?

Saxenda® contain the active ingredient liraglutide, similar to a naturally occurring hormone called GLP-1 that is released from the intestine after a meal.

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

- **a BMI of 30 or more (obese), or**
- **a BMI of 27 or more 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').**

Saxenda® should be used with a reduced calorie diet and increased physical activity.

BMI (Body Mass Index) is a simple measure of your weight in relation to your height. It is calculated by dividing your weight in kg by your height in metres squared.

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.

Weight loss normally starts within 2 weeks and continues for 9 to 12 months on Saxenda® treatment. Saxenda® may then help you to maintain this new lower weight and help to prevent weight being regained.

Saxenda® is not addictive.

2. What should I know before I use Saxenda®?

Warnings

Do not use Saxenda® if:

- You are allergic to liraglutide, or any of the ingredients listed at the end of this leaflet.
  Some of the symptoms of an allergic reaction may include:
  - redness, swelling, rash and itching at the injection site
  - rash, itching or hives on the skin
  - shortness of breath
  - wheezing or difficulty breathing
  - swelling of the face, lips, tongue or other parts of the body.
- Always check the ingredients to make sure you can use this medicine
- Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes
- It is after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering
- It has expired or is damaged, return it to your pharmacist for disposal. The expiry date refers to the last day of that month.

Check with 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.
- you have diabetes. Do not use Saxenda® as a replacement for insulin. Saxenda® and insulin should not be used together.
- you have heart failure (disease of the heart with shortness of breath, and swelling of the feet or legs due to fluid build-up). The use of Saxenda® is not recommended if you have severe heart failure.
- you are taking any other weight loss medications, including prescription, over the counter or herbal medicines.
- you have inflammatory bowel disease, such as Crohn's disease.
- you have gastroparesis (a condition in which your stomach has difficulty in emptying food properly).
- you currently have or have had thyroid disease, including thyroid nodules and enlargement of the thyroid gland.
- you have kidney disease or are on dialysis (a treatment where your blood is filtered and purified using a machine).
- you have liver problems
- you have or have had a disease of the pancreas.
- you have or have had depression, suicidal thoughts or any other major mental illness.
- you have other medical conditions or have taken other medicines that may have caused you to gain weight.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Use of this medicine in pregnancy has not been studied. Saxenda® should not be used during pregnancy. It is not known if Saxenda® may harm your unborn child.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known if Saxenda® passes into breast milk. Do not use Saxenda® if you are breast-feeding.

Effects on the digestive system

Drink plenty of fluids to avoid dehydration, particularly if you experience vomiting or diarrhoea when beginning treatment with Saxenda®.
Dehydration can cause kidney problems that sometimes require dialysis.

Inflammation of the pancreas

Stop taking Saxenda® and contact a doctor immediately if you experience severe pain in your upper abdomen, usually worse on the right side under the ribs.

The pain may be felt through to your back or right shoulder. If you lose substantial weight, you are at risk of gallstones and thereby inflamed gallbladder.

Food or liquid getting into lungs during anaesthesia

Some patients taking medicines like Saxenda® have had problems with food or liquid from their stomach getting into their lungs while under general anaesthesia or deep sedation.

Tell your healthcare professional that you are taking Saxenda® before you have a procedure that requires general anaesthesia or deep sedation.

Children and adolescents

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

Use in the elderly

There is little experience with Saxenda® in patients ≥ 75 years old. It is not recommended if you are 75 years or older.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Saxenda® and affect how it works.

In particular, tell your doctor or pharmacist if you are using the following medicines:

- for the treatment of type 2 diabetes, such as a sulfonylurea (including 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.
- to thin your blood (anticoagulants), such as warfarin or other types of medicines called ‘coumarin derivatives’. Your doctor may need to monitor you more closely.
- for high blood pressure, such as amlodipine, atenolol or bisoprolol or for heart disease, such as digoxin.
- for HIV, such as atazanavir or ritonavir.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Saxenda®.

4. How do I use Saxenda®?

Your doctor or pharmacist will have given you advice on how to use your medicine. Carefully follow all the directions. They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor, nurse or pharmacist for help.

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

How much to use

Your doctor will tell you how much of this medicine you need to use each day.

- The usual starting dose is 0.6 mg once a day.
- Your doctor will tell you how long to keep taking this dose. It will be for at least one week.
- Your dose may then be increased 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 to inject**
Week 1	0.6 mg once a day

Week	Dose to inject
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.

Visit your doctor on a regular basis to assess your need for continued treatment with Saxenda®.

Do not change your dose unless your doctor has told you to.

Follow the instructions provided and use Saxenda® until your doctor tells you to stop.

When to use Saxenda®

You can use Saxenda® at any time of day, with or without food and drinks. It is preferable to use Saxenda® at about the same time each day, at a time that is most convenient for you.

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. Consult your doctor before you continue.

How to use Saxenda®

Before you use the pen for the first time, your doctor or nurse will show you how to use the pen.

- Saxenda® pre-filled pen is designed to be used with NovoFine® needles, up to a length of 8 mm. Needles are not included with the pen.
- Ask your doctor or nurse which needle width (gauge) and length is best for you.
- Use a new needle for each injection and dispose of it after use.
- Saxenda® is given as an injection under the skin (subcutaneous injection) as shown to you by your doctor or nurse. **Never inject Saxenda® into a vein or muscle.**
- Saxenda® may be injected into the front of your waist (abdomen), the front of your thigh, or your upper arm.
- Change the place within the area where you inject each day to reduce the risk of developing lumps under the skin. See Section 6. Are there any side effects?

Checking your Saxenda® pen:

Saxenda® should be clear and colourless.

Do not use this medicine if it is thickened, coloured, or has solid bits in it.

Follow the detailed instructions on how to inject Saxenda® in the instructions for use supplied with the product. These instructions are also available via the following hyperlinks:

https://medsinfo.com.au/media/noisaxen

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 Saxenda® 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 an extra dose or increase the dose on the following day to make up for the missed dose.

If you are not sure what to do, talk to your doctor, nurse or pharmacist.

If you use too much Saxenda® (overdose)

You should immediately:

- phone the Poisons Information Centre **(by calling 13 11 26 in Australia; 0800 764 766 in New Zealand),** or
- contact your doctor, or
- go to the Accident and Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

Take the medicine pack with you. You may need medical treatment. Using too much Saxenda® may cause nausea (feeling sick), vomiting (being sick), or low blood sugar (hypoglycaemia), see Section 6. Are there any side effects? for the early warning signs of hypos.

5. What should I know while using Saxenda®?

Things you should do

Tell your doctor if you have diabetes.

They may adjust the dose of your diabetes medicine to prevent you getting ‘hypos’ (low blood sugar levels).

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

Tell your doctor, nurse or pharmacist if you are travelling.

Ask them for a letter explaining why you are taking injecting devices with you. Each country you visit will need to see this letter, so you should take several copies.

You may not be able to get Saxenda® in the country you are visiting.

Your doctor, nurse or pharmacist can provide you with some helpful information.

Remind any doctor, dentist or pharmacist or other health professional you visit that you are using Saxenda®.

Things you should not do

Do not stop using your medicine unless your doctor tells you to.

Do not use the medicine if you think it has been frozen or exposed to excessive heat.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not share needles or pens.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how the Saxenda® affects you.

For further information talk to your doctor or pharmacist.

Looking after your medicine

- Store Saxenda® pens that are not being used between 2°C and 8°C in a refrigerator (not in or too near the freezer section or cooling element). Do not freeze.
- When Saxenda® is being used, you can keep the pen for 1 month either at room temperature (below 30#C) or in a refrigerator (2°C to 8°C), away from the cooling element. Store the pen without a needle attached.

- The medicine in Saxenda® must not be frozen, or exposed to heat or direct sunlight.
- When you are not using the pen, keep the pen cap on in order to protect it from light.

Follow the instructions in the carton on how to take care of your medicine properly.

Keep it where young children cannot reach it.

When to discard your medicine

Discard Saxenda® after 1 month even if there is still some medicine left in it.

Do not use Saxenda® after the expiry date printed on the pen label and carton. The expiry date refers to the last day of that month.

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

Getting rid of any unwanted medicine

Dispose of used needles safely into a yellow plastic sharps container.

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
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: • changed sense of taste • dizziness • indigestion (dyspepsia)	**Speak to your doctor if you have any of these less serious side effects and they worry you.**

Less serious side effects	What to do
• inflammation in the lining of the stomach (gastritis) • feeling bloated, burping, wind (flatulence), or dry mouth • heartburn • stomach discomfort • upper stomach pain • gall stones • low blood sugar (a 'hypo') • injection site reactions (such as bruising, pain, irritation, itching and rash) • feeling weak or tired • difficulty sleeping (insomnia) This usually occurs during the first 3 months of treatment • increase of pancreatic enzymes (such as lipase and amylase) • rash. **Uncommon:** may affect up to 1 in 100 people: • fast heartbeat • feeling generally unwell	

Less serious side effects	What to do
• inflamed gall bladder • allergic reactions including skin rash • delay in the emptying of the stomach • loss of fluids (dehydration) This is more likely to occur at the start of treatment and may be due to you being sick (vomiting), feeling sick (nausea), and diarrhoea. **Not known:** frequency cannot be estimated from the available data • Infection of the urinary tract • Increase in liver blood test results • Lumps under the skin may be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). • hair loss	

Less serious side effects	What to do
• change in skin sensation Saxenda® may not work very well if you inject into a lumpy area. Change the injection site with each injection to help prevent this skin change.	

Hypoglycaemia

Hypos are more likely to occur if you have diabetes and are also taking a sulfonylurea. A hypo may come on suddenly. The warning signs of a hypo can include:

- cold sweat, cool pale skin
- headache
- fast heartbeat
- feeling sick
- feeling very hungry
- changes in vision
- feeling sleepy
- feeling weak, nervous, anxious, or confused
- difficulty concentrating
- shaking (tremor)

Your doctor can provide you with further information about how to treat low blood sugar levels and what to do if you notice these warning signs. If you are already

taking a sulfonylurea when you start using Saxenda® your doctor may tell you to reduce the dose of the sulfonylurea.

Serious side effects

Serious side effects	What to do
Inflamed pancreas (pancreatitis) • severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting. Pancreatitis is a serious, potentially life-threatening medical condition. **Stop taking Saxenda® if you experience this.** **Reduced kidney function** • signs may include reduction in urine volume, a metallic taste in your mouth and bruising easily. **Gallbladder problems**	**Call your doctor straight away, or go straight to the Accident and Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
• signs may include upper right side abdominal pain, yellowing of the skin and eyes or clay coloured stools **Severe allergic reactions** (anaphylaxis). Symptoms include: • skin rashes over a large part of the body • shortness of breath, wheezing • swelling of the face, lips or tongue • fast pulse • sweating **Mood changes** • depression or any mental changes (especially sudden changes in mood, behaviours, thoughts or feelings) that are new, worse or worry you. **Goitre** • a lump or swelling in your neck, hoarseness,	

Serious side effects	What to do
trouble swallowing, or shortness of breath. • These side effects are rare. **Bowel obstruction*** • A severe form of constipation with additional symptoms such as stomach ache, bloating, vomiting etc. *frequency not known **Loss of vision** • A medical condition of the eye called non-arteritic anterior ischaemic optic neuropathy (NAION), which may cause loss of vision to one of your eyes without any pain.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Saxenda® contains

Active ingredient **(main ingredient)**	liraglutide 6 mg/mL
Other ingredients **(inactive ingredients)**	• phenol • dibasic sodium phosphate dihydrate • Propylene glycol • sodium hydroxide • hydrochloric acid • water for injections.

Do not take this medicine if you are allergic to any of these ingredients.

What Saxenda® looks like

Saxenda® is supplied as a clear and colourless solution for injection in a pre-filled pen. Each pen contains 3 mL of solution, and is able to deliver doses of 0.6 mg, 1.2 mg, 1.8 mg, 2.4 mg or 3.0 mg.

Saxenda® is available in packs containing 1, 3 or 5 pens. Not all pack sizes may be marketed.

Needles are not included.

AUST R 225804

Who distributes Saxenda®

Australia

Novo Nordisk Pharmaceuticals Pty. Ltd.

Level 10

118 Mount Street

North Sydney NSW 2060

New Zealand

Novo Nordisk Pharmaceuticals Ltd.

PO Box 51-268

Pakuranga

Auckland

New Zealand

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Further information

Always check the following websites to ensure you are reading the most recent version of the Saxenda® consumer medicine information:

Australia

www.novonordisk.com.au

https://www.ebs.tga.gov.au/

New Zealand

www.novonordisk.co.nz

www.medsafe.govt.nz/

For further information call Novo Nordisk Customer Care on 1800 668 626 (AU) or 0800 733 737 (NZ).

For further dietary advice, refer to the dietary guidelines on the NH&MRC website at www.nhmrc.gov.au (Australia), or the current food and nutrition guidelines on the Ministry of Health website at www.health.govt.nz (New Zealand).

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