

Package leaflet

Victoza® 6 mg/ml solution for injection in pre-filled pen

Liraglutide

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, nurse or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

In this leaflet:

1. What Victoza® is and what it is used for
2. What you need to know before you use Victoza®
3. How to use Victoza®
4. Possible side effects
5. How to store Victoza®
6. Further information

1. WHAT VICTOZA® IS AND WHAT IT IS USED FOR

Victoza® contains the active substance liraglutide. It helps your body reduce your blood sugar level only when blood sugar is too high. It also slows food passage through your stomach.

Victoza® is used on its own if your blood sugar is not properly controlled by diet and exercise alone or with other medicines for diabetes when they are not enough to control your blood sugar levels. These may include: oral antidiabetics (such as metformin, pioglitazone, sulphonylurea medicines, sodium glucose cotransporter 2 inhibitor (SGLT2i)) and/or insulin.

Victoza® is used in addition to standard of care therapy to prevent heart disease if you are at an increased risk for heart disease and have elevated blood sugar levels.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE VICTOZA®

Do not use Victoza®

- if you are allergic (hypersensitive) to liraglutide or any of the other ingredients of Victoza® (listed in section 6, 'What Victoza® contains').

Take special care with Victoza®

Talk to your doctor, pharmacist or nurse:

- before using Victoza®
- if you have or have had a disease of the pancreas.

This medicine should not be used if you have type 1 diabetes (your body does not produce any insulin) or diabetic ketoacidosis (a complication of diabetes with high blood sugar and increase in effort to breathe). It is not an insulin and should therefore not be used as a substitute for insulin.

There is no experience with this medicine in patients with severe kidney problems. If you are on dialysis, consult your doctor.

The use of Victoza[®] is not recommended if you have severe heart failure.

This medicine is not recommended if you have a severe stomach or gut problem which results in delayed stomach emptying (called gastroparesis), or inflammatory bowel disease.

If you have symptoms of acute pancreatitis, such as persistent, severe stomach ache, you should consult your doctor immediately (see section 4).

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

When initiating treatment with Victoza[®], you may in some cases experience loss of fluids/dehydration, e.g. in case of vomiting, nausea and diarrhoea. It is important to avoid dehydration by drinking plenty of fluids. Contact your doctor if you have any questions or concerns.

Children and adolescents

Victoza[®] should not be used in children and adolescents under 18 years.

Using other medicines

Please tell your doctor, nurse or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

In particular, tell your doctor, nurse or pharmacist if you are using medicines for diabetes containing any of the following active substances:

- Sulphonylurea (such as glimepiride or glibenclamide) and/or insulin. You may get hypoglycaemia (low blood sugar) when using Victoza[®] together with a sulphonylurea and/or insulin. When you first start using these medicines together, your doctor may tell you to lower the dose of the sulphonylurea or insulin. Please, see section 4 for the warnings signs of low blood sugar. If you are also taking a sulphonylurea (such as glimepiride or glibenclamide) and/or insulin, your doctor may tell you to test your blood sugar levels. This will help your doctor to decide if the dose of the sulphonylurea and/or insulin needs to be changed.
- Warfarin or other oral anti-coagulation medicines. More frequent blood testing to determine the ability of your blood to clot may be required.

Using Victoza[®] with food and drink

You can use Victoza[®] regardless of meals.

Pregnancy and breast-feeding

Tell your doctor if you are, you think you might be, or are planning to become pregnant. Victoza[®] should not be used during pregnancy. It is not known if Victoza[®] may harm your unborn child.

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

Ask your doctor or pharmacist for advice before taking any medicine if you are pregnant or breast-feeding.

Driving and using machines

While you are driving or using tools or machines, you should avoid getting low blood sugar (hypoglycaemia), because this may reduce your ability to concentrate. Your doctor will tell you how to do this.

3. HOW TO USE VICTOZA®

Always use Victoza® exactly as your doctor has told you. You should check with your doctor, nurse or pharmacist if you are not sure.

- The starting dose is **0.6 mg** once a day, for at least one week.
- Your doctor will tell you when to increase it to **1.2 mg** once a day.
- Your doctor may tell you to further increase the dose to **1.8 mg** once a day, if your blood glucose is not adequately controlled with a dose of 1.2 mg.

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

Victoza® is given as an injection under the skin (subcutaneously). Do not inject it into a vein or muscle. The best places to give yourself the injection are the front of your thighs, the front of your waist (abdomen), 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 4).

You can give yourself the injection at any time of the day, regardless of meals. When you have found the most convenient time of the day it is preferred that you inject Victoza® around the same time of the day.

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

Detailed instructions for use are provided on the other side of this leaflet.

If you use more Victoza® than you should

If you use more Victoza® than you should, talk to your doctor, pharmacist or the national poisons centre (0800 POISON or 0800 764766) straight away. You may need medical treatment. If you use too much Victoza®, you may experience nausea, vomiting or low blood sugar (hypoglycaemia). Please refer to 'Common side effects' for early warning signs of low blood sugar.

If you forget to use Victoza®

If you forget a dose, use Victoza® as soon as you remember.

However, if it is more than 12 hours since you should have used Victoza®, skip the missed dose. Then take your next dose as usual the following day.

Do not take an extra dose or increase the dose on the following day to make up for the missed dose.

If you stop using Victoza®

Do not stop using Victoza® without talking to your doctor. If you stop using it, your blood sugar levels may increase.

If you have any further questions on the use of this medicine, ask your doctor, nurse or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Victoza® can cause side effects although not everybody gets them.

Side effects may occur with certain frequencies, which are defined as follows:

- Very common: affects more than 1 user in 10
- Common: affects 1 to 10 users in 100
- Uncommon: affects 1 to 10 users in 1,000
- Rare: affects 1 to 10 users in 10,000
- Very rare: affects less than 1 user in 10,000
- Not known: frequency cannot be estimated from the available data.

Very common side effects

- Nausea (feeling sick). This usually goes away over time.
- Diarrhoea. This usually goes away over time.

Common side effects

- Hypoglycaemia (low blood sugar). The warning signs of low blood sugar may come on suddenly and can include: cold sweat, cool pale skin, headache, fast heart beat, feeling sick, feeling very hungry, changes in vision, feeling sleepy, feeling weak, nervous, anxious, confused, difficulty concentrating, shaking (tremor). Your doctor will tell you how to treat low blood sugar and what to do if you notice these warning signs. This is more likely to happen if you already take a sulphonylurea or insulin. Your doctor may reduce dose of these medicines before you start using Victoza®.
- Anorexia
- Decreased appetite
- Headache
- Feeling dizzy
- Vomiting
- Dyspepsia
- Inflamed stomach (gastritis). The signs include stomach pain, nausea and vomiting.
- Gastro-oesophageal reflux disease (GORD). The signs include heartburn.
- Abdominal distension
- Abdominal pain upper
- Constipation
- Wind (flatulence)
- Eructation
- Upper respiratory tract infection
- Injection site reactions (such as bruising, pain, irritation, itching and rash)
- Allergic reactions like rash
- Increased heart rate
- Feeling tired
- Increase of pancreatic enzymes (such as lipase and amylase).

Uncommon side effects

- Allergic reactions like pruritus (itching) and urticaria (a type of skin rash)
- Malaise (feeling unwell)
- Dehydration, sometimes with a decrease in kidney function
- Gallstones
- Inflamed gallbladder
- Change in how things taste
- Delay in the emptying of the stomach.

Rare side effects

- A severe form of allergic reaction (anaphylactic reaction) with additional symptoms such as breathing problems, swelling of throat and face, fast heart beat, etc. If you experience these symptoms you should seek immediate medical help and inform your doctor as soon as possible.

- Bowel obstruction. A severe form of constipation with additional symptoms such as stomach ache, bloating, vomiting etc.

Very rare

- Cases of inflammation of the pancreas (pancreatitis). Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking Victoza® 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).

Not known

- Lumps under the skin may be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). Liraglutide 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.
- Infection of the urinary tract

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, nurse or pharmacist.

5. HOW TO STORE VICTOZA®

Keep out of the reach and sight of children.

Do not use Victoza® 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 opening:

Store in a refrigerator (2°C–8°C). Keep away from the cooling element. Do not freeze.

During use:

You can keep the pen for 1 month when stored at a temperature below 30°C or in a refrigerator (2°C–8°C), away from the cooling element. Do not freeze.

When you are not using the pen, keep the pen cap on in order to protect from light.

Do not use Victoza® if the solution is not clear and colourless, or almost colourless.

6. FURTHER INFORMATION

What Victoza® contains

- The active substance is liraglutide. One 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 and water for injections.

What Victoza® looks like and contents of the pack

Victoza® is supplied as a clear, colourless or almost colourless solution for injection in pre-filled pen. Each pen contains 3 ml of solution, delivering 30 doses of 0.6 mg, 15 doses of 1.2 mg or 10 doses of 1.8 mg.

Victoza® is available in packs containing 1, 2 or 3 pens. Not all pack sizes may be marketed.

For further information call Novo Nordisk Customer Care on 0800 733 737.

www.novonordisk.co.nz

You can also get more information about diabetes from Diabetes New Zealand:

www.diabetes.org.nz

Sponsor

Victoza® is supplied in New Zealand by:

Novo Nordisk Pharmaceuticals Ltd.

11-19 Customs Street West,

Commercial Bay Tower,

Level 18, Office 1834

Auckland 1010

New Zealand.

This leaflet was prepared on 04 April 2024.

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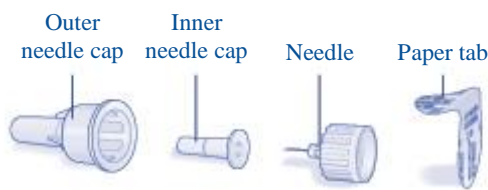
Instructions for using the Victoza[®] pen

Please read these instructions carefully before using your pen.

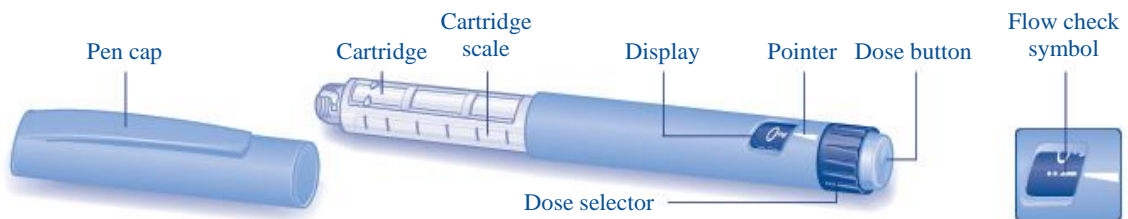
Your pen comes with 18 mg of liraglutide. You can select doses of 0.6 mg, 1.2 mg and 1.8 mg.

The pen is designed to be used with NovoFine[®] disposable injection needles up to a length of 8 mm and as thin as 32G (0.25/0.23 mm).

Needle (example)



Victoza[®] Pen



Prepare your pen

Check the name and coloured label of your pen to make sure that it contains liraglutide. Using the wrong medicine could cause severe harm.

Pull off the pen cap.



Pull off the paper tab from a new disposable needle. Screw the needle straight and tightly onto your pen.





Pull off the outer needle cap and keep it for later.




Pull off the inner needle cap and dispose of it.



 **Always use a new needle for each injection.** This reduces the risk of contamination, infection, leakage of liraglutide, blocked needles and inaccurate dosing.

 Be careful not to bend or damage the needle.

 Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.

Caring for your pen

- Do not try to repair your pen or pull it apart.
- Keep your pen away from dust, dirt and all kinds of liquids.
- Clean the pen with a cloth moistened with a mild detergent.
- Do not try to wash, soak or lubricate it – this can harm the pen.

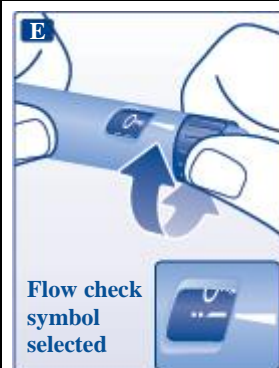
Important information

- Do not share your pen or needles with anyone else.
- Keep your pen out of the reach of others, especially children.

With each new pen, check the flow

Check the flow before your first injection with each new pen. If your pen is already in use, go to ‘Select your dose’, step H.

Turn the dose selector until the flow check symbol lines up with the pointer.



Hold the pen with the needle pointing up. Tap the cartridge gently with your finger a few times. This will make any air bubbles collect at the top of the cartridge.




Keep the needle pointing up and press the dose button until 0 mg lines up with the pointer.

A drop of liraglutide should appear at the needle tip. If no drop appears, repeat steps E to G up to four times.

If there is still no drop of liraglutide, change the needle and repeat steps E to G once more.

Do not use the pen if a drop of liraglutide still does not appear. This indicates the pen is defective and you must use a new one.



 If you have dropped your pen against a hard surface or suspect that something is wrong with it, always put on a new disposable needle and check the flow before you inject.

Select your dose

Always check that the pointer lines up with 0 mg.

Turn the dose selector until your needed dose lines up with the pointer (0.6 mg, 1.2 mg or 1.8 mg).

If you selected a wrong dose by mistake, simply change it by turning the dose selector backwards or forwards until the right dose lines up with the pointer.

Be careful not to press the dose button when turning the dose selector backwards, as liraglutide may come out.

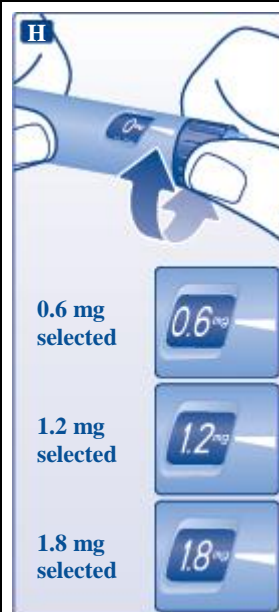
If the dose selector stops before your needed dose lines up with the pointer, there is not enough liraglutide left for a full dose. Then you can either:




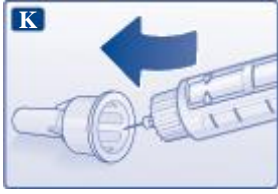

Split your dose into two injections:

Turn the dose selector in either direction until 0.6 mg or 1.2 mg lines up with the pointer. Inject the dose. Then prepare a new pen for injection and inject the remaining number of mg to complete your dose.

You may only split your dose between your current pen and a new pen if trained or advised by your healthcare professional. Use a calculator to plan the doses. If you split the dose wrong, you may inject too much or too little liraglutide.

Inject the full dose with a new pen:



<p>If the dose selector stops before 0.6 mg lines up with the pointer, prepare a new pen and inject the full dose with the new pen.</p>	
<p> Do not try to select other doses than 0.6 mg, 1.2 mg or 1.8 mg. The numbers in the display must line up precisely with the pointer to ensure that you get the correct dose.</p> <p>The dose selector clicks when you turn it. Do not use these clicks to select your dose.</p> <p>Do not use the cartridge scale to measure how much liraglutide to inject – it is not accurate enough.</p>	
<p>Inject your dose</p> <p>Insert the needle into your skin using the injection technique shown by your doctor or nurse. Then follow the instructions below:</p> <p>Press the dose button to inject until 0 mg lines up with the pointer. Be careful not to touch the display with your other fingers or press the dose selector sideways when you inject. This is because it may block the injection.</p> <p>Keep the dose button pressed down and leave the needle under the skin for at least 6 seconds. This is to make sure that you get your full dose.</p>	
<p>Pull out the needle.</p> <p>After that, you may see a drop liraglutide at the needle tip.</p> <p>This is normal and does not affect your dose.</p>	
<p>Guide the needle tip into the outer needle cap without touching the needle or the outer needle cap.</p>	
<p>When the needle is covered, carefully push the outer needle cap completely on. Then unscrew the needle. Dispose of it carefully and put the pen cap back on.</p> <p>When the pen is empty, carefully dispose of it without a needle attached. Please dispose of the pen and needle in accordance with local requirements.</p>	



Always remove the needle after each injection, and store your pen without a needle attached.



This reduces the risk of contamination, infection, leakage of liraglutide, blocked needles and inaccurate dosing.



Caregivers must **be very careful when handling used needles** – to prevent needle injury and cross-infection.