

PATIENT MEDICATION INFORMATION

READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

PrVictoza[®] **liraglutide injection**

Read this carefully before you start taking **Victoza[®]** and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about **Victoza[®]**.

Serious Warnings and Precautions

Possible Risk of thyroid tumours, including cancer

As part of drug testing, liraglutide, the active ingredient in **Victoza[®]** was given to rats and mice in long term studies. In these studies, liraglutide caused both rats and mice to develop medullary thyroid tumours, some of which were cancer. It is not known if **Victoza[®]** will cause thyroid tumours or a type of thyroid cancer called medullary thyroid cancer in people. Medullary thyroid cancer in humans is rare; however, it is serious and potentially fatal. If you develop tumours of the thyroid, it may have to be surgically removed. You should discuss any safety concerns you have about the use of **Victoza[®]** with your doctor.

What is **Victoza[®] used for?**

- **Victoza[®]** is used in combination with metformin, with metformin and a sulfonylurea, with metformin and a sodium glucose cotransporter 2 inhibitor (SGLT2i), or basal insulin to improve blood sugar levels in adults with type 2 diabetes.
- **Victoza[®]** is used in combination with metformin with or without basal insulin to improve blood sugar levels in adolescents and children aged 10 years and above with type 2 diabetes.
- **Victoza[®]** may be used on its own if your blood sugar is not properly controlled by diet and exercise alone and you cannot use metformin.
- If you have type 2 diabetes and have a history of heart disease (such as a past heart attack, heart failure, or stroke), **Victoza[®]** can be used along with diet and exercise to lower your risk of dying from events related to your heart or blood vessels.
- **Victoza[®]** should not be used in type 1 diabetes (formerly known as insulin-dependent diabetes mellitus or IDDM).

How does **Victoza[®] work?**

Victoza[®] belongs to a class of medicines called GLP-1 analogue. **Victoza[®]** helps your body to make more insulin when your blood sugar is high.

What is type 2 diabetes?

Type 2 diabetes is a condition in which your body does not make enough insulin, and/or does not use the insulin that your body produces as well as it should. When this happens, sugar (glucose) builds up in the blood. This can lead to serious problems.

What are the ingredients in **Victoza[®]?**

Medicinal ingredients: Liraglutide

Non-medicinal ingredients: Disodium phosphate dihydrate, propylene glycol, phenol and water for injections

Victoza® comes in the following dosage forms:

Pre-filled multidose pen that can deliver 30 doses of 0.6 mg, 15 doses of 1.2 mg or 10 doses of 1.8 mg.

Do not use Victoza® if:

- You or a member of your family has ever had medullary thyroid cancer.
- You have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- You are allergic to any of the ingredients in Victoza®.
- You are pregnant or breastfeeding.

To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Victoza®. Talk about any health conditions or problems you may have, including if you:

- Or a member of your family has or has had medullary thyroid carcinoma, or if you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Have type 1 diabetes.
- Have ever had diabetic ketoacidosis (increased ketones in the blood or urine).
- Have ever had an allergic reaction to Victoza®.
- Have a high heart rate (fast pulse).
- Have a condition called heart block.
- Have any heart disease, such as angina, heart rhythm disturbances or congestive heart failure; or if you have ever had a myocardial infarction (heart attack).
- Have kidney problems.
- Have liver problems.
- Have gastrointestinal (digestive) problems.
- Have ever had pancreatitis.
- Are breastfeeding or plan to breastfeed.
- Are pregnant or plan to become pregnant.
- Have severe vomiting and/or diarrhea and/or dehydration.

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

Victoza® may increase heart rate and could cause changes known as PR prolongation, which are detected by electrocardiogram (ECG) tracings. Increased heart rate is the same as a faster pulse. Rarely, drugs with these effects can cause changes in heart rhythm that could result in dizziness, palpitations (a feeling of rapid, pounding, or irregular heart beat), fainting or death. These heart rhythm changes are more likely if you have heart disease, or if you are taking certain other drugs. It is important to follow your doctor's advice about the dose of Victoza® or about any special tests that you may need. See '*What are possible side effects from using Victoza®?*'

Victoza® is not recommended for use in children under 10 years of age.

Driving and Using Machines

While you are driving or using tools or machines, you should avoid getting low blood sugar (hypoglycemia), because this may reduce your ability to concentrate. Talk to your doctor for further information. Do not drive or operate machinery if you feel dizzy.

Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.

In particular, tell your doctor, Diabetes Nurse Educator or pharmacist if you are using any of the following medicines for diabetes:

- A sulfonylurea medicine (such as glibenclamide or glimepiride). This is because using Victoza[®] at the same time may cause your blood sugar to get too low (hypoglycemia).
- When you first start using these medicines together, your doctor may tell you to lower the dose of the sulfonylurea medicine.
- Insulin. You may get hypoglycemia (low blood sugar) when using Victoza[®] with insulin as insulin increases the risk of hypoglycemia. See '*What are possible side effects from using Victoza[®]?*'
- If you are not sure if the medicines you are taking contain a sulfonylurea, ask your doctor, Diabetes Nurse Educator or pharmacist.

The following may interact with Victoza[®]:

The following list includes some, but not all, of the drugs that may increase the risk of heart rhythm problems while receiving Victoza[®]. You should check with your doctor or pharmacist before taking any other medication with Victoza[®]:

- Drugs to treat hypertension
- Drugs to treat heart failure
- Drugs to treat HIV infection
- Drugs to treat attention deficit-hyperactivity disorder
- Drugs to suppress appetite/cause weight loss
- Decongestants
- Drugs to treat asthma

How to take Victoza[®]:

Take Victoza[®] exactly as your doctor has prescribed.

Victoza[®] is an injection which is given under the skin (subcutaneously). Do not inject it into a vein or muscle.

Before you use the pen for the first time, your doctor or Diabetes Nurse Educator will show you how to use it. 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. You can give yourself the injection at any time of the day. (See '*Instructions for using the Victoza[®] (liraglutide injection) pen*').

Do not share your Victoza[®] pen with anyone else, even if the needle is changed. Do not reuse or share needles with another person including family members. You may give another person an infection or get an infection from them.

Usual dose:

Victoza® can be taken at any time of the day. It does not matter when you take it in relation to meals.

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 be increased to 1.2 mg once a day if your blood glucose is not under control. If your blood glucose is not controlled with a dose of 1.2 mg, your doctor may tell you to increase the dose to 1.8 mg once a day. Do not change your dose unless your doctor has told you to.

You will not need to test your blood sugar levels each day in order to adjust your dose of Victoza®. However, if you are taking a sulfonylurea medicine as well as Victoza®, your doctor may advise you to test your blood sugar levels. This will help your doctor to decide if the dose of the sulfonylurea needs to be changed.

For children and adolescents starting Victoza®, your doctor may advise you to test your blood sugar levels to monitor for hypoglycemia (low blood sugar).

Overdose:

If you think you have taken too much Victoza®, contact your healthcare professional, hospital emergency department or regional poison control centre immediately, even if there are no symptoms.

If you use more Victoza® than you should, talk to your doctor straight away. You may need medical treatment. If you use too much Victoza® you may feel sick (have nausea), become sick (vomit), or experience low blood sugar (hypoglycemia). Please refer to '*Common (affects less than 1 in 10 people)*' for early warning signs of low blood sugar.

Missed Dose:

If a dose of Victoza® is missed take your dose on the next day as usual. Do not take an extra dose or increase the dose on the following day to make up for the missed dose.

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

What are possible side effects from using Victoza®?

These are not all the possible side effects you may feel when taking Victoza®. If you experience any side effects not listed here, contact your healthcare professional.

Like all medicines, Victoza® can cause side effects. The following side effects may happen with this medicine.

Very common (affects more than 1 in 10 people)

- Feeling sick (nausea). This usually goes away over time.
- Diarrhea

Common (affects less than 1 in 10 people)

- Low blood sugar (hypoglycemia). This is usually mild. It is more likely if you are also taking a medicine for diabetes called a sulfonylurea. The warning signs of low blood sugar may come on suddenly. They 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, or 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. If you are already taking a sulfonylurea medicine when you start using Victoza[®], your doctor may tell you to reduce the dose of the sulfonylurea.
- Anorexia
- Decreased appetite
- Headache
- Feeling dizzy
- Being sick (vomiting)
- Burping
- Indigestion
- Inflamed stomach (gastritis). The signs include stomach pain, feeling sick (nausea) and being sick (vomiting)
- Gastro-esophageal reflux disease (GERD). The signs include heartburn.
- Painful or swollen tummy (abdomen)
- Constipation
- Wind (flatulence)
- Infection of the upper airways
- Injection site reactions (such as bruising, pain irritation, itching and rash)
- Increased heart rate
- Gallstones
- Inflamed gallbladder (upper abdominal pain after eating, nausea, bloating and indigestion, especially after consuming a fatty meal)

Uncommon (affects less than 1 in 100)

- Urticaria (a type of skin rash)
- Change in how things taste

Unknown

- Delay in the emptying of the stomach
- Lumps under the skin may be caused by build-up of a protein called amyloid (cutaneous amyloidosis). Victoza[®] 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.

If any of the side effects do not go away or get worse, or if you notice any side effects not listed in the leaflet, please tell your doctor, Diabetes Nurse Educator or pharmacist.

Serious side effects and what to do about them			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
UNCOMMON Chest pain or symptoms of a possible heart rhythm disturbance / dizziness, palpitations, fainting or seizures, you should seek immediate medical attention		✓	✓
RARE Pancreatitis / persistent, severe abdominal pain with or without vomiting		✓	
Severe hypoglycemia / disorientation, loss of consciousness, and seizures		✓	✓
Severe form of allergic reaction (anaphylactic reaction) with symptoms of breathing problems, swelling of throat and face, and fast heart beat. You should seek immediate medical attention		✓	✓
Cases of inflammation of the pancreas (pancreatitis). Pancreatitis can be a serious, potentially life-threatening medical condition. Stop taking Victoza® and contact your 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 your back, as well as nausea and vomiting, as it could be a sign of an inflamed pancreas (pancreatitis).		✓	✓
VERY RARE Thyroid tumour / lump in the neck, difficulty in swallowing, difficulty in breathing or persistent hoarseness		✓	
UNKNOWN Cutaneous amyloidosis: lumps under the skin		✓	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough

to interfere with your daily activities, talk to your healthcare professional.

Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on Adverse Reaction Reporting (<https://www.canada.ca/en/health-canada/services/drugs-health-products/medeffect-canada.html>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.

Storage:

Keep out of reach and sight of children.

Do not use Victoza[®] after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

- Before you start to use Victoza[®], store it in a refrigerator (2°C-8°C) away from the freezer compartment. Do not freeze it.
- When Victoza[®] is being used, you can keep it for 1 month either at room temperature (not above 30°C) or in a refrigerator (2°C-8°C).
- Do not use Victoza[®] if it has been frozen.
- Do not use Victoza[®] if it is not clear and colourless.
- Always remove the injection needle after each injection and store your Victoza[®] pen without an injection needle attached. This prevents contamination, infection, and leakage. It also ensures that the dosing is accurate.
- When you are not using the pen, keep the cap on. This will protect the medicine from light.
- Protect Victoza[®] from high temperatures and sunlight.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

If you want more information about Victoza[®]:

- Talk to your healthcare professional
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/drug-product-database.html>); the manufacturer's website (<http://www.novonordisk.ca>), or by calling Novo Nordisk Canada Inc., at 1-800-465-4334.

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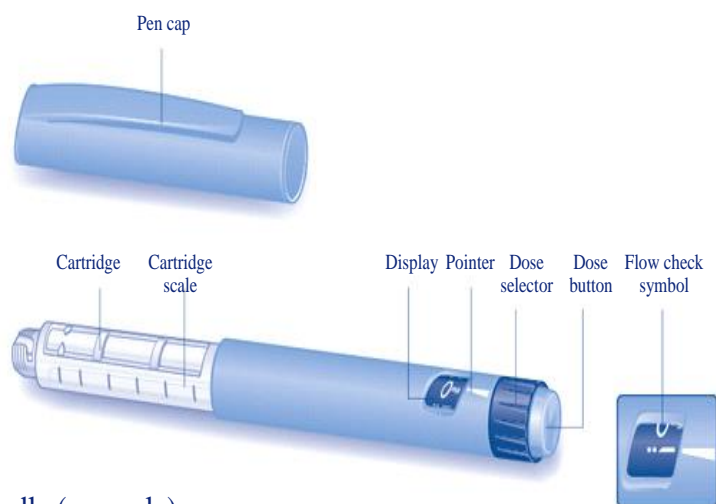
Instructions for using the Victoza® (liraglutide injection) pen

Please read these instructions carefully before using your Victoza® pen.

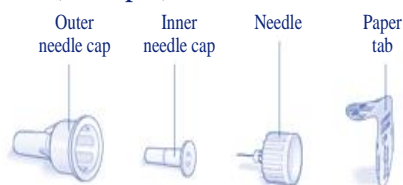
Your Victoza® pen comes with 18 mg of liraglutide. You can select doses of 0.6 mg, 1.2 mg and 1.8 mg. Victoza® pen is designed to be used with NovoFine® disposable needles up to a length of 8 mm and as thin as 32G.

Do not share your Victoza® pen with another person, even if the needle is changed. Do not reuse or share needles with another person including family members. You may give another person an infection, or get an infection from them.

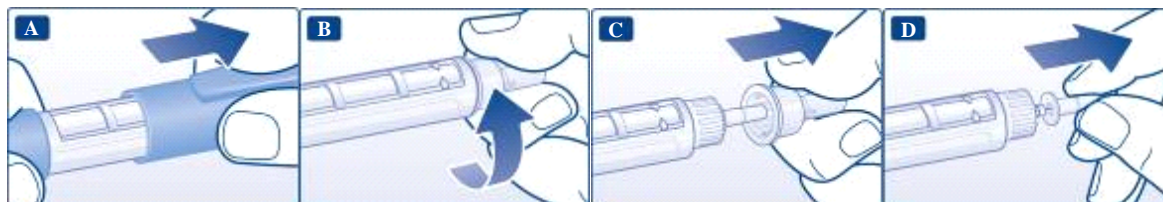
Victoza® pen



Needle (example)



Preparing your Victoza® 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.

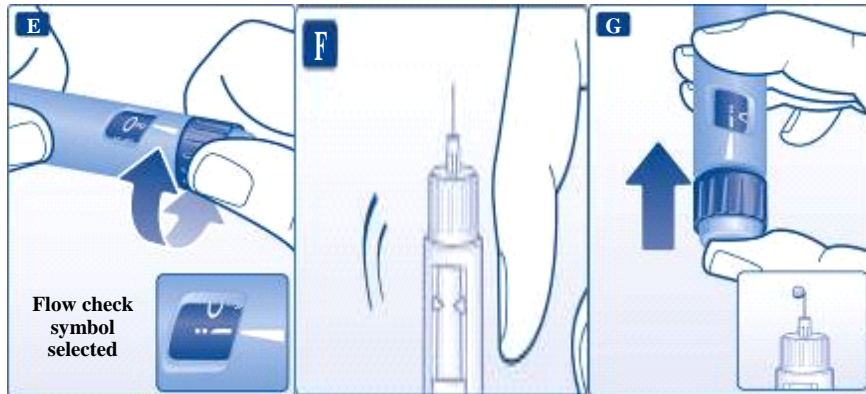
A. Pull off the pen cap.

- B. Pull off the paper tab from a new disposable needle. Screw the needle straight and tightly onto your pen.
- C. Pull off the outer needle cap and keep it for later.
- D. Pull off the inner needle cap and throw it away.

- **Always use a new needle for each injection. This reduces the risk of** contamination, infection, leakage of liraglutide, blocked needles and inaccurate dosing. Do not reuse or share needles with another person.
- Be careful not to bend or damage the needle.
- Never put the inner needle cap back on when you have removed it from the needle. This reduces the risk of hurting yourself with the needle.

With each new pen, check the liraglutide flow

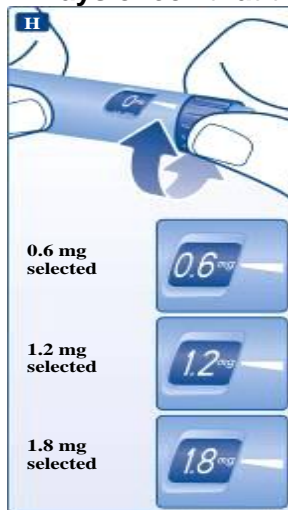
Always check the liraglutide flow before your first injection with each new pen as follows. If your pen is already in use, go to “Select your dose” Step H.



- E. Turn the dose selector until the flow check symbol lines up with the pointer.
 - F. 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.
 - G. 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.

Selecting your dose

Always check that the pointer lines up with 0 mg.



- H. 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:

Divide 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. 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.

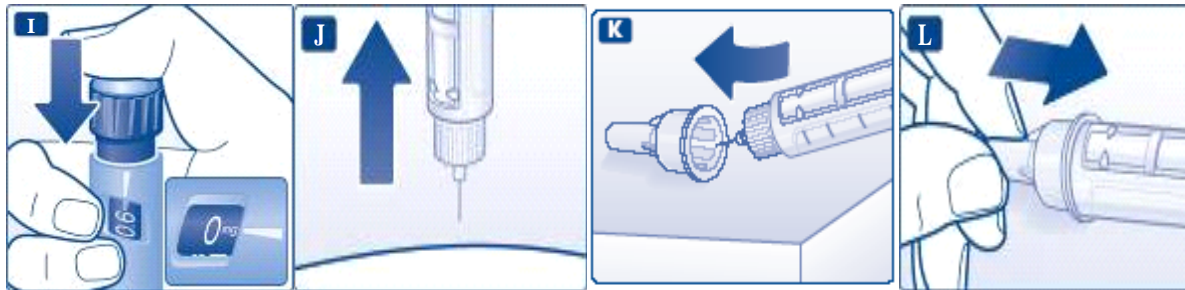
Inject the full dose with a new pen:

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.

- The dose selector clicks when you turn it. You must not use these clicks to select the amount of liraglutide to inject.
- Do not use the cartridge scale to measure how much liraglutide to inject – it is not accurate enough.
- 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 a correct dose.

Using your injection

Insert the needle into your skin using the injection technique shown by your doctor or nurse. Then follow the instructions below:



- I. 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. Keep the dose button pressed down and leave the needle under the skin for at least six seconds. This is to make sure that you get your full dose.
 - J. Pull out the needle.
After that, you may see a drop of liraglutide at the needle tip.
This is normal and has no effect on the dose you have just had.
 - K. Guide the needle tip into the outer needle cap without touching the outer needle cap.
 - L. 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. 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.
- Always remove the needle after each injection and store your Victoza[®] pen without a needle attached.
 - This prevents contamination or infection or leakage of liraglutide. It also ensures that the dosing is accurate.
 - Caregivers should be very careful when handling used needles to avoid hurting themselves with the needles.

Caring for your Victoza[®] pen

Your Victoza[®] pen is accurate and safe to use. But you must take care of it:

- 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 it, soak it or lubricate it – this can harm the pen.

Important information

- Do not share your Victoza[®] pen with anyone else.
Keep your Victoza[®] pen out of reach of others, especially children.