APPROVED PATIENT INFORMATION LEAFLET (PIL):

VICTOZA

SCHEDULING STATUS

S4

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

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

Keep this leaflet as you may need to read it again.

If you have further questions, please ask your doctor or your pharmacist.

Victoza has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

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 a medicine called liraglutide

- Each millilitre (ml) of the solution for injection contains 6 mg of liraglutide (produced by recombinant DNA technology in *Saccharomyces cerevisiae*).
- Each pre-filled pen contains 3 ml equivalent to 18 mg sodium-free anhydrous liraglutide, a human Glucagon-like Peptide-1 (GLP-1) analogue.
- The other ingredients are disodium phosphate dihydrate, propylene glycol, phenol and water for injections.

Victoza is used for the treatment of the type of diabetes called 'type 2 diabetes mellitus'.

Victoza is indicated as an adjunct to diet and exercise to achieve glycaemic control in patients with type 2 diabetes mellitus. Victoza is indicated for once-daily administration as:

- monotherapy
- combination therapy with one or more oral antidiabetic medicines (metformin, sulphonylureas, sodium-glucose cotransporter 2 inhibitor (SGLT2i) or a thiazolidinedione) and/or insulin when previous therapy does not achieve adequate glycaemic control.

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 have type 1 diabetes mellitus

- if you are allergic (hypersensitive) to liraglutide or any of the other ingredients of Victoza
- if you are pregnant or intend to become pregnant
- if you previously had an inflammation of the pancreas
- if you have severe kidney disease or are on dialysis

• Take special care with Victoza

Tell your doctor or healthcare professional before being given the Victoza injection if:

- You have or have had a disease of the pancreas (inflammation of the pancreas)
- You have thyroid disease including thyroid nodules and enlargement of the thyroid gland.
- You have severe kidney disease or are on dialysis

- There is no experience with Victoza in patients with severe kidney problems.

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

- Victoza 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 tell your doctor or healthcare professional immediately.

- When initiating treatment with Victoza, you may 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. Tell your doctor or healthcare professional if you have any questions or concerns.

Children and adolescent

Victoza is not recommended for children and young people under 18 years.

Using Victoza with food and drink

You can use Victoza at any time of day. It does not matter when you take it in relation to meals.

Pregnancy and breastfeeding

- Victoza is contraindicated in pregnancy and breastfeeding.
- You should not use Victoza if you are pregnant or breastfeeding your baby.
- Tell your doctor before using Victoza if you are pregnant or might become pregnant.
- If you are being treated with Victoza, you should not breastfeed your baby.
- If you are pregnant or breastfeeding your baby while using Victoza please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery

- Victoza is not likely to affect your ability to drive or use any tools or machines.
- You should make sure that you know how Victoza affects you before you drive or use machinery.
- While you are driving or using tools or machines, you should avoid getting low blood sugar (hypoglycaemia). Your doctor will tell you how to do this.

Taking other medicines with Victoza

Always tell your healthcare professional if you are taking any other medicine. This includes complementary or traditional medicines as using Victoza at the same time with another medicine may cause undesirable interactions.

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

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

- Insulin
- A sulphonylurea medicine (such as glimepiride or glibenclamide). This is because using Victoza at the same time may cause your blood sugar to get too low (hypoglycaemia).
- When you first start using these medicines together, your doctor may tell you to lower the dose of the sulphonylurea medicine.

- If you are not sure if the medicines you are taking contain a sulphonylurea, ask your doctor or pharmacist.

3. How to use VICTOZA

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

The Victoza pen

Victoza is a pen which is used to inject doses of 0,6 mg, 1,2 mg or 1,8 mg once a day.

- Each pen contains more than one dose, so it can be used more than once.
- Do not share your pen with anyone else.

Injection needles

- Injection needles are not included with Victoza.
- Victoza is designed to be used with NovoFine or NovoTwist injection needles, up to a length of 8 mm and as thin as 32 G.
- Ask your doctor or diabetes nurse which injection needle width (gauge) and length is best for you.
- Use a new injection needle for each injection and dispose of it after use.

Using Victoza

- 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 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 (see section 4 'Possible side effects').

You can give yourself the injection at any time of the day.

How much to inject

- 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 will then be increased to 1,2 mg once a day.
- 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.
Do not use more than 1,8 mg per day.

Testing your blood sugar levels

- 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 sulphonylurea medicine as well as Victoza, your doctor may tell you to test your blood

sugar levels to begin with. This will help your doctor to decide if the dose of the sulphonylurea needs to be changed.

If you inject more Victoza than you should

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), be sick (vomit) or experience low blood sugar (hypoglycaemia). Please refer to 'Common side effects' for early warning signs of low blood sugar.

If you forget to inject/missed a dose of Victoza

- If you forget a dose, inject Victoza as soon as you remember it.
- 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 administer an extra dose or increase the dose on the following day to make up for the missed dose.

Effect when treatment with Victoza is stopped

Do not stop administering Victoza without telling your doctor. If you stop using it, your blood sugar levels may increase.

Do not share your Victoza with any other person, it is prescribed for you.

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

4. POSSIBLE SIDE EFFECTS

Victoza can have side effects.

Not all side effects reported for Victoza are included in this leaflet. Should your general health worsen while using Victoza, please consult your doctor, pharmacist or other healthcare professional for advice.

The following side effects may happen with Victoza:

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

Frequent

- Feeling sick (nausea). This usually goes away over time.
- Diarrhoea
- Headache
- Being sick (vomiting)
- Burping
- Indigestion
- Inflamed stomach (gastritis). The signs include stomach pain, feeling sick (nausea) and being
- sick (vomiting).
- Gastro-oesophageal reflux disease (GORD), that includes heartburn.
- Painful or swollen tummy (abdomen)

- Constipation
- Wind (flatulence)
- Anorexia
- Decreased appetite
- Infection of the upper airways
- Low blood sugar (hypoglycaemia). 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 sulphonylurea medicine when you start using Victoza, your doctor may tell you to reduce the dose of the sulphonylurea.

Less frequent

- Pancreatitis (inflammation of the pancreas). 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).

Thyroid events - like nodules, increased blood calcitonin, goitres and cancer.

Since the market introduction of Victoza, additional side effects have been reported:

- increased pulse rate
- urticaria (a type of rash)
- pruritus (itching)
- malaise (feeling unwell)
- dehydration, sometimes with a decrease in kidney function.
- injection site reactions (such as bruising, pain, irritation, itching and rash)
- Increased lipase/amylase
- Fatigue (feeling tired)
- Cholelithiasis/Cholecystitis (Gallstones/inflamed gallbladder)

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.

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

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of VICTOZA.

5. How to store VICTOZA

- Keep all medicines out of the 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 to 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 to 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 Victoza from light.
- Protect Victoza from high temperatures and sunlight.
- Keep out of reach and sight of children.

Disposal

Medicines should not be disposed of via waste water or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

Pre-filled (multidose, disposable) light blue pen, comprising of a slim pen-shaped injector assembled with a cartridge (3 ml). The cartridge is made of colourless glass (type 1), containing a bromobutyl rubber closure shaped as a plunger and closed with a bromobutyl/ polyisoprene rubber closure. The pen injector is made of polyolefin and polyacetal.

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.
Pack sizes of 2 or 3 pens are packed in a cardboard box.

Victoza comes as a colourless or almost colourless liquid

(solution for injection) in a glass cartridge inside a pen injector.

The solution is not cloudy and does not contain any particles.

REGISTRATION NUMBER

43/21.13/0781

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DATE OF PUBLICATION

23 October 2023

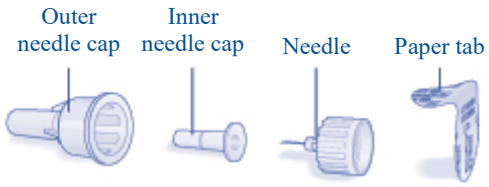
Instructions for using the Victoza® pen

Please read these instructions carefully before using your pen.

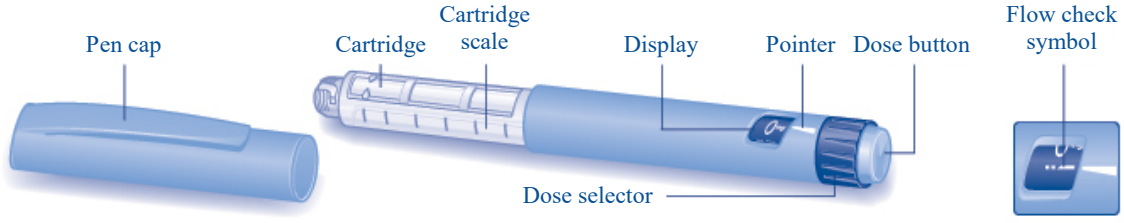
Your pen comes with 18 mg of liraglutide. You can select doses of 0.6 mg, 1.2 mg and 1.8 mg.

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

Needle (example)



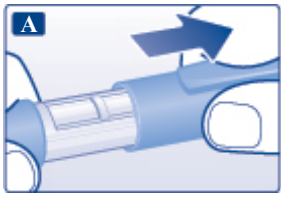
Victoza® Pen



Prepare your pen

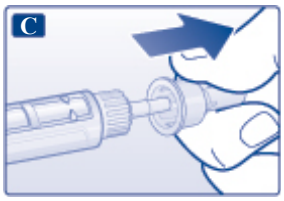
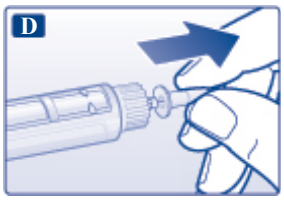
Check the name and coloured label of your pen to make sure that it contains liraglutide. Using the wrong medicine could cause severe harm.

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.

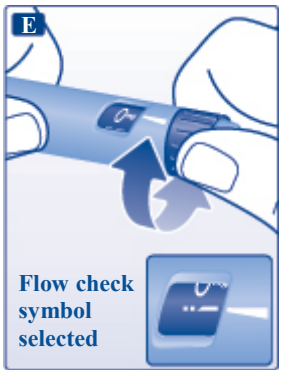
⚠ Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.

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 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:

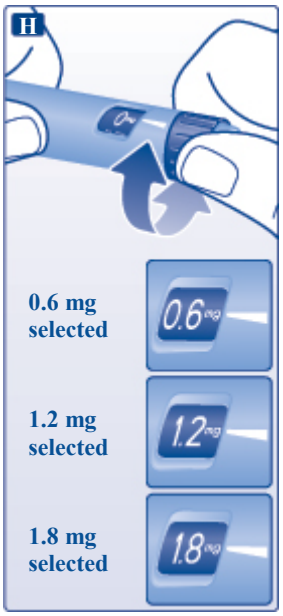
Split your dose into two injections:

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:

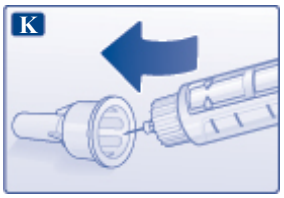
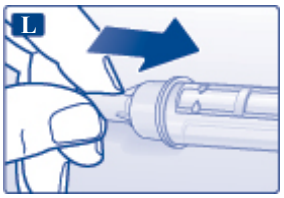
If the dose selector stops before 0.6 mg lines up with the pointer, prepare a new pen and inject the full dose with the new pen.



⚠ 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.

The dose selector clicks when you turn it. Do not use these clicks to select your dose.

Do not use the cartridge scale to measure how much liraglutide to inject – it is not accurate enough.

Inject your dose **Insert the needle into your skin using the injection technique shown by your doctor or nurse. Then follow the instructions below:** 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 6 seconds. This is to make sure that you get your full dose.	
Pull out the needle. After that, you may see a drop liraglutide at the needle tip. This is normal and does not affect your dose.	
Guide the needle tip into the outer needle cap without touching the needle or the outer needle cap.	
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 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.