

PACKAGE LEAFLET: INFORMATION FOR THE USER

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. 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 to treat type 2 diabetes mellitus when:

- metformin or a sulphonylurea alone (such as glimepiride or glibenclamide) despite the maximal tolerated dose are not enough to control your blood sugar levels.
- metformin in combination with a sulphonylurea (such as glimepiride or glibenclamide) or metformin in combination with a glitazone (such as rosiglitazone or pioglitazone) are not enough to control your blood sugar levels.

2. 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

- if you are also taking a sulphonylurea (such as glimepiride or glibenclamide), your doctor may tell you to test your blood sugar levels. This will help your doctor to decide if the dose of the sulphonylurea needs to be changed.

Victoza should not be used if you have type 1 diabetes or diabetic ketoacidosis. Victoza should not be used in children and adolescents under 18 years.

The use of Victoza is not recommended in patients with inflammatory bowel disease and/or diabetic gastroparesis.

If you have symptoms of acute pancreatitis, like persistent, severe abdominal pain, you should consult your doctor.

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:

- insulin. Victoza is not recommended if you are using insulin.
- a sulphonylurea (such as glimepiride or glibenclamide). You may get hypoglycaemia (low blood sugar) when using Victoza together with a sulphonylurea as sulphonylurea increases the risk of hypoglycaemia. When you first start using these medicines together, your doctor may tell you to lower the dose of the sulphonylurea medicine. Please, see section 4 for the warnings signs of low blood sugar.

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 (subcutaneous). 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.

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 straight away. You may need medical treatment. If you use too much Victoza, you may experience nausea or vomit.

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. 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.
- Headache
- Vomiting
- Indigestion
- Inflamed stomach (gastritis). The signs include stomach pain, nausea and vomiting.
- Gastro-oesophageal reflux disease (GORD). The signs include heartburn.
- Painful or swollen tummy (abdomen)
- Abdominal discomfort
- Viral infection in stomach
- Constipation
- Wind (flatulence)
- Decreased appetite
- Bronchitis
- Common cold
- Dizziness
- Fatigue
- Fever
- Toothache
- Injection side reactions (such as bruising, pain, irritation, itching, and rash)

Uncommon side effects

- Pancreatitis

Rare side effects

- Angioedema

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). Do not freeze. Keep away from the freezer compartment.

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 freezer compartment. 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.

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 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, 3, 5 or 10 pens. Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Novo Nordisk A/S
Novo Allé
DK-2880 Bagsværd
Denmark

This leaflet was last approved in 06/2009

Detailed information on this medicine is available on the European Medicines Agency (EMA) website: <http://www.emea.europa.eu/>.

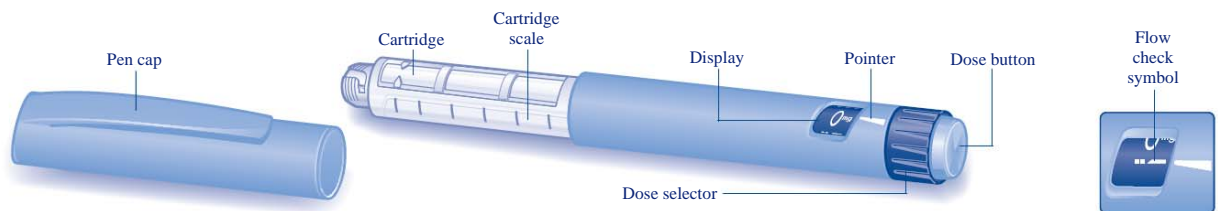
Instructions for using the Victoza pen

Please read these instructions carefully before using your Victoza pen.

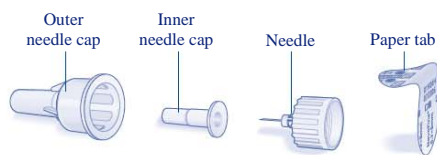
Your Victoza pen comes with 18 mg of liraglutide. You can select doses of 0.6 mg, 1.2 mg and 1.8 mg.

Victoza pen is designed to be used with NovoFine or NovoTwist disposable injection needles up to a length of 8 mm and as thin as 32G.

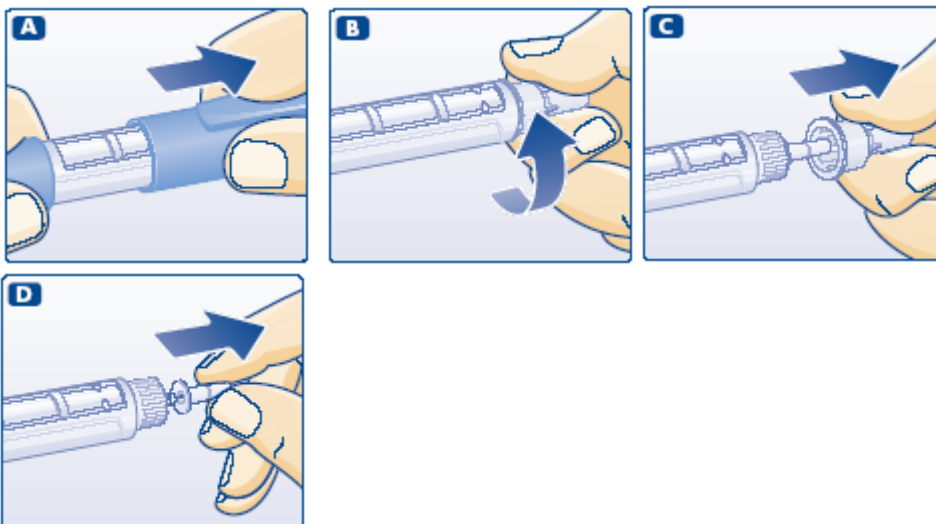
Victoza® Pen



Needle (example)



Preparing your Victoza pen



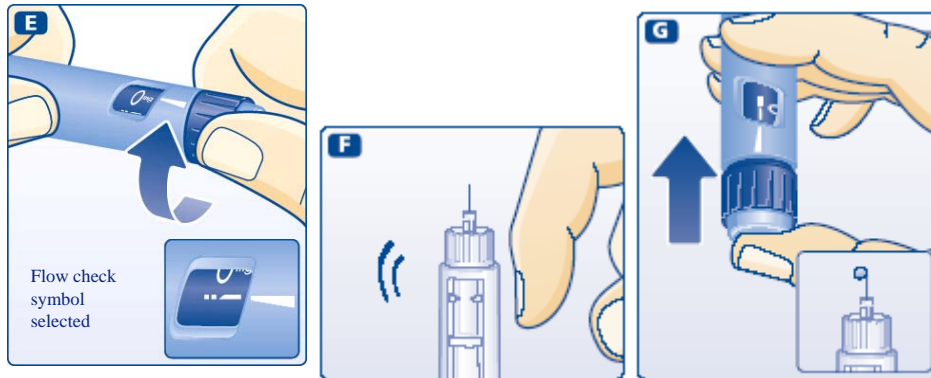
- A. Pull off the pen cap.
- B. Pull off the paper tab from a new disposable needle. Screw the needle straight and tightly onto your pen.
- C. Pull off the outer needle cap and keep it for later.

D. Pull off the inner needle cap and throw it away.

- △ Always use a new needle for each injection to prevent contamination.
- △ 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.

Checking the flow

Always check the flow as follows before you inject with a new pen.



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

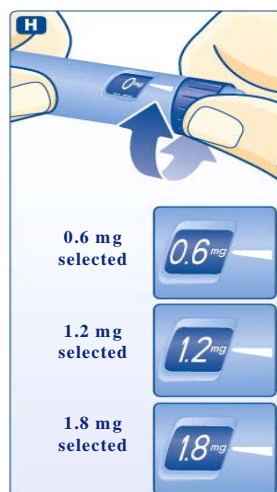
F. Hold the pen with the needle pointing up. Tap the cartridge gently with your finger a few times. This will make any air bubbles collect at the top of the cartridge.

G. Keep the needle pointing up and press the dose button until 0 mg lines up with the pointer. Repeat steps **E** to **G** until a drop of liraglutide appears at the needle tip. If no drop appears after six times, change the needle and repeat steps **E** to **G** up to six more times. If you still see no drop of liraglutide, the pen is broken 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.

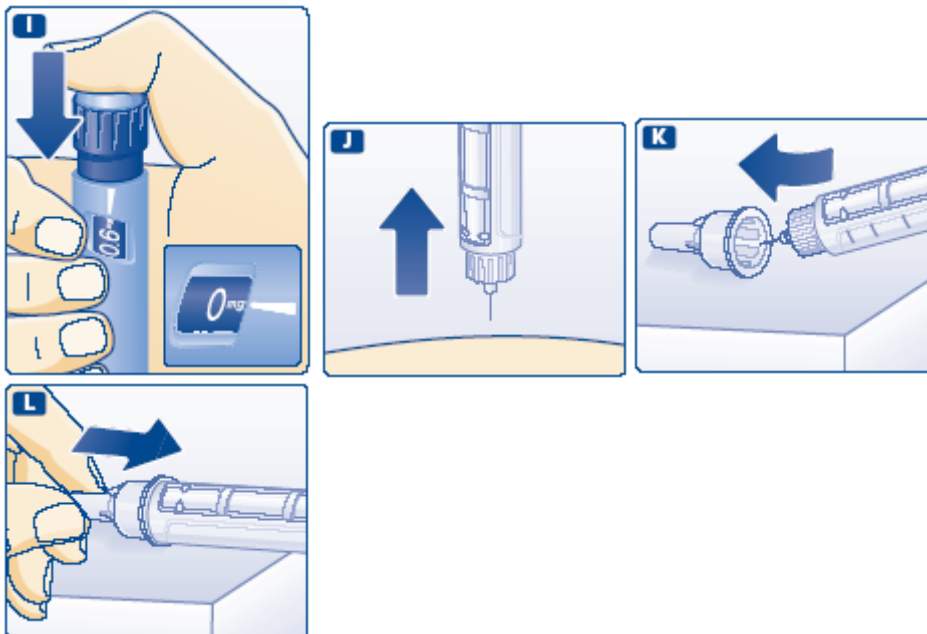
Inject the full dose with a new pen:

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 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. Carefully throw the needle away and put the pen cap back on. When the pen is empty, carefully throw it away without a needle attached. Please throw the pen and needle away 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.