Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Victoza
Solution for injection in pre-filled pen
Active ingredient: liraglutide 6 mg/ml

Inactive ingredients and allergens in the medicine: see section 2 "Important information about some of this medicine's ingredients" and section 6 "Additional information".

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Victoza is indicated for treatment of adults, adolescents and children aged 10 years and above with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise:
1. As monotherapy when you cannot use metformin (another medicine for the treatment of diabetes)
2. In addition to other medicines for the treatment of diabetes

Therapeutic group: medicines for treatment of diabetes, GLP-1 analogs.
Victoza contains the active substance liraglutide. It helps your body reduce your blood sugar level only when the blood sugar level is too high. It also slows food passage through your stomach and may help prevent heart disease.

2. Before using this medicine

Do not use this medicine if:

- You are sensitive (allergic) to liraglutide or to any of the other ingredients in this medicine (see section 6 "Additional information").

Special warnings about using this medicine
Before treatment with Victoza, tell your doctor if:

- you have or have had a disease of the pancreas
- you are using insulin, your doctor will tell you how to reduce the dose of insulin and will recommend you to monitor your blood sugar level more frequently, in order to avoid hyperglycemia (high blood sugar level) and diabetic ketoacidosis (a complication of diabetes with high blood sugar level and increase in effort to breathe, that occurs when the body is unable to break down glucose due to lack of insulin).

This medicine should not be used if you have type 1 diabetes (your body does not produce any insulin) or diabetic ketoacidosis. Victoza is not an insulin and should therefore not be used as a substitute for insulin.

The use of Victoza is not recommended if you are on dialysis treatment.
The use of Victoza is not recommended if you have severe liver disease.
The use of Victoza is not recommended if you have severe heart failure.

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

If you have symptoms of acute pancreatitis, such as persistent, severe abdominal pain, 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 diarrhea. 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 can be used in adolescents and children aged 10 years and above. No data are available in children below 10 years of age.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.
Particularly if you are taking:

- Sulfonylurea (such as glimepiride or glibenclamide) or insulin. You may develop hypoglycemia (low blood sugar level) when using Victoza together with a sulfonylurea or insulin, as sulfonylurea and insulin increase the risk of hypoglycemia. When you first start using these medicines together, your doctor may tell you to lower the dose of the sulfonylurea or insulin. Please see section 4 for the warning signs of low blood sugar level. If you are also taking a sulfonylurea (such as glimepiride or glibenclamide) or insulin, your doctor may tell you to test your blood sugar levels. The test will help your doctor to decide if the dose of the sulfonylurea 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.

Pregnancy and breastfeeding
Tell your doctor if you are pregnant, think you might be pregnant or are planning to become pregnant. Victoza should not be used during pregnancy because it is not known if it may harm your unborn child.

It is not known if Victoza passes into breast milk, therefore do not use this medicine if you are breastfeeding.

Driving and using machines
Low blood sugar level (hypoglycemia) may reduce your ability to concentrate. Avoid driving or using machines if you experience signs of hypoglycemia. Please see section 4 for the warning signs of low blood sugar level. Please consult your doctor for further information on this topic.

Important information about some of this medicine's ingredients
This medicine contains less than 1 mmol sodium (23 mg) per dose, this means that it is essentially "sodium free".

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.
Only your doctor will determine your dose and how you should take this medicine. The recommended dosage is usually:

- The starting dose is 0.6 mg once a day, for at least one week.

- Your doctor will tell you when to increase the dose 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.

Do not exceed the recommended dose.

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 injection 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 have accidentally taken a higher dose
If you have injected more Victoza than you should, talk to your doctor straight away or go to a hospital emergency room and bring the medicine package with you. You may need medical treatment. You may experience nausea, vomiting or diarrhea.
If a child has accidentally swallowed or taken some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine
If you forget to inject the medicine at the scheduled time, inject Victoza as soon as you remember. However, if it is more than 12 hours since you should have injected Victoza, skip the missed dose. Then, inject the next dose as usual on the following day.
Do not inject a double dose or increase the dose on the following day to make up for the missed dose.

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine
Even if your health improves, do not stop using Victoza without talking to your doctor. If you stop using it, your blood sugar level may increase.

Do not take medicines in the dark! Check the label and dose <u>every time</u> you take a medicine. Wear glasses if you need them.
If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Victoza may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Serious side effects
Common: may affect up to 1 in 10 users

- Hypoglycemia (low blood sugar level). The warning signs of low blood sugar level may appear suddenly and may include: cold sweat, cool pale skin, headache, fast heartbeat, nausea, feeling of increased hunger, changes in vision, feeling sleepy, feeling weak, nervousness, anxiety, confusion, difficulty concentrating, shaking (tremor). Your doctor will tell you how to

treat low blood sugar level and what to do if you notice these warning signs. This effect is more likely to happen if you also take a sulfonylurea or insulin. Your doctor may reduce the dose of these medicines before you start using Victoza.

Rare: may affect up to 1 in 1,000 users

- A severe allergic reaction (anaphylactic reaction) with additional symptoms such as breathing difficulties, swelling of throat and face, fast heartbeat, etc. If you experience these symptoms, you should seek immediate medical help and inform your doctor as soon as possible.
- Bowel obstruction. Severe constipation with additional symptoms such as abdominal pain, bloating, vomiting etc.

Very rare: may affect up to 1 in 10,000 users

- Cases of inflammation of the pancreas (pancreatitis). Pancreatitis can be a serious, potentially life-threatening disease. 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 radiate to your back, as well as nausea and vomiting, as it could be a sign of inflammation of the pancreas (pancreatitis).

Additional side effects

Very common: may affect more than 1 in 10 users

- Nausea. This effect usually resolves over time.
- Diarrhea. This effect usually resolves over time.

Common:

- Vomiting.

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.

- Headache
- Indigestion
- Inflammation in the stomach (gastritis). The signs include abdominal pain, nausea and vomiting.
- Gastro-oesophageal reflux disease (GORD). The signs include heartburn.
- Painful or swollen abdomen
- Abdominal discomfort
- Constipation
- Gas in the gastrointestinal tract
- Decreased appetite
- Bronchitis
- Common cold
- Dizziness
- Increased pulse
- Tiredness
- Toothache
- Injection site reactions (such as injury, pain, irritation, itching and rash)
- Increase in pancreatic enzymes (such as lipase and amylase).

Uncommon: may affect up to 1 in 100 users

- Allergic reactions like pruritus (itching) and urticaria
- Dehydration, sometimes with a decrease in kidney function
- Malaise (feeling unwell)

- Gallstones
- Inflammation of the gallbladder
- Slowing of gastric emptying.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link:
https://sideeffects.health.gov.il

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.
- Do not use the medicine after the expiry date (exp. date) which is stated on the injection pen label and the carton. The expiry date refers to the last day of that month.
- Before opening: Store in a refrigerator (2˚C to 8˚C). Do not freeze. Keep away from the freezer compartment.
- During use: You can keep the injection pen for 1 month at a temperature below 30˚C or in a refrigerator (2˚C to 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 this medicine if the solution is not clear and colorless or almost colorless.
- Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, this medicine also contains:

Propylene glycol, phenol, disodium phosphate dihydrate, sodium hydroxide, hydrochloric acid and water for injections**.**

What Victoza looks like and contents of the pack:

- Victoza is supplied as a clear, colorless or almost colorless solution for injection in a pre-filled injection pen. One injection pen contains 18 mg liraglutide. Each injection 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 supplied in packs containing 1, 2 or 3 injection pens.
Not all pack sizes may be marketed.
The pack of 1 injection pen is available with or without needles.
Needles are not included in the rest of the packs.

Registration holder's name and address:
Novo Nordisk Ltd.
1 Atir Yeda St., Kfar-Saba, 4464301

Manufacturer's name and address:
Novo Nordisk A/S
Novo Allé, DK-2880, Bagsværd, Denmark

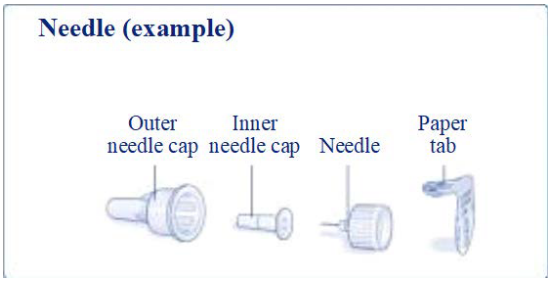
This leaflet was revised in October 2020.

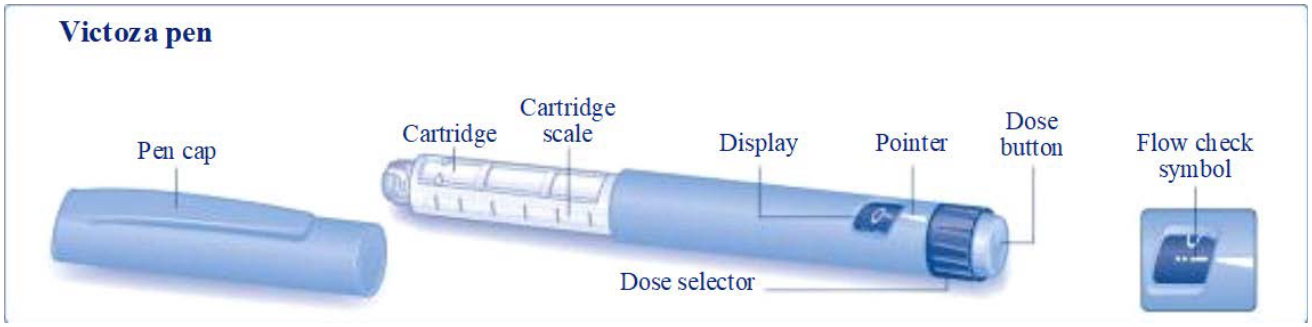
Registration number of the medicine in the National Drug Registry of the Ministry of Health: 143-07-32987-00

Instructions for using the Victoza pen

Please read these instructions carefully before using your Injection pen.

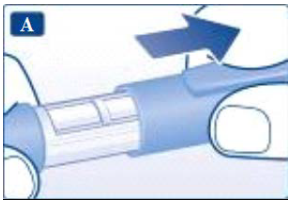
Your injection pen is supplied with 18 mg of liraglutide.
You can select doses of 0.6 mg, 1.2 mg and 1.8 mg.
The injection pen is designed to be used with NovoFine or NovoTwist disposable injection needles up to a length of 8 mm and thickness of 32G (0.25/0.23 mm).





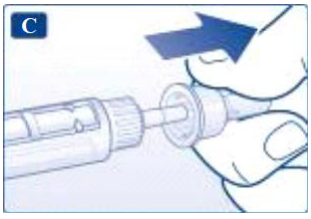
Prepare your injection pen

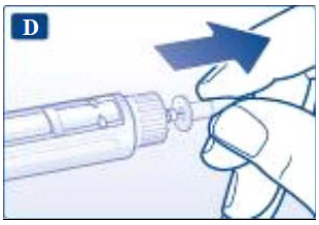
Check the name and label color of your pen to make sure that it contains liraglutide. Using the wrong medicine may cause severe harm.
Remove the injection pen cap.



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

Remove the outer needle cap and keep it for later.



Remove the inner needle cap and dispose of it.	

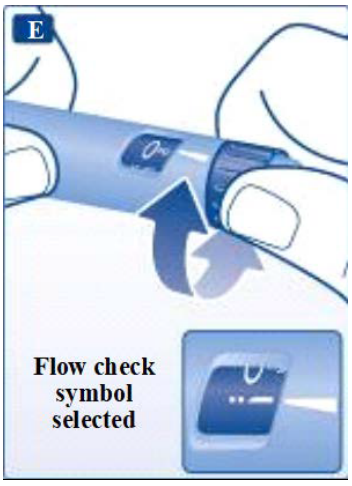
⚠ Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of liraglutide, blocked needles and inaccurate dosing.
⚠ Be careful not to bend or damage the needle.
⚠ Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.

Caring for your injection pen

- Do not try to repair or dismantle your injection pen.
- Keep your injection pen away from dust, dirt and all kinds of liquids.
- Clean the injection pen with a cloth moistened with a mild detergent.
- Do not try to wash, soak or lubricate it – these actions may harm the injection pen.

⚠ **Important information**

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

With each new injection pen, check the flow **Check the flow before your first injection with each new injection 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 your injection pen with the needle pointing up. Tap the cartridge gently with your finger a few times. Tapping 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 injection pen if a drop of liraglutide still does not appear. This indicates that the injection pen is defective and you must use a new injection pen.

⚠ If you have dropped your injection pen against a hard surface or suspect that something is defective in 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 the dose required for you 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.

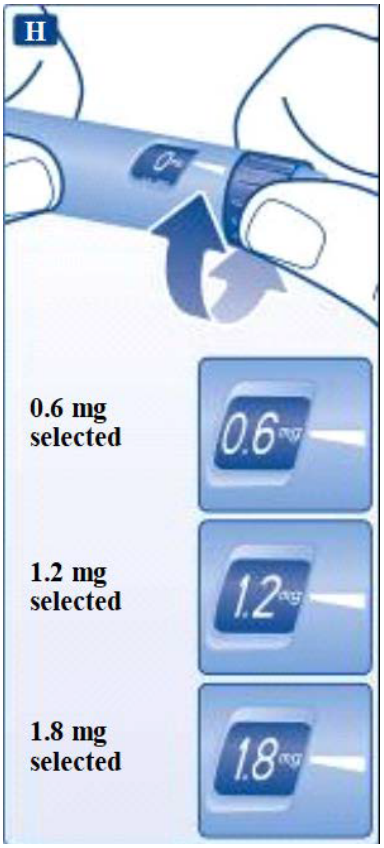
Be careful not to press the dose button when turning the dose selector backwards, as liraglutide may come out.

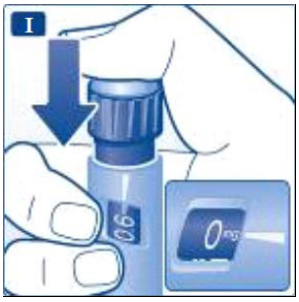
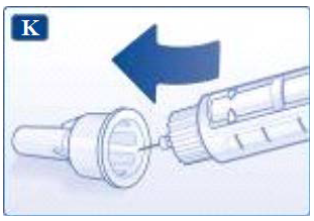
If the dose selector stops before the dose required for you lines up with the pointer, there is not enough liraglutide left for a full dose. In this situation you can either:

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 injection pen for injection, and inject the remaining number of mg to complete your dose.

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

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



with the new injection pen.	
⚠ Do not try to select doses other 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 "click" sounds 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, since these actions 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 the needle out of the skin. After that, you may see a drop liraglutide at the needle tip. This is normal and does not affect your dose.	
Insert 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 to cover it completely. Then unscrew the needle. Dispose of the needle carefully and cover your injection pen with the injection pen cap. When the injection pen is empty, carefully dispose of it without a needle attached. Dispose of the injection pen and needle in accordance with local requirements.	

⚠ Always remove the needle after each injection, and store your injection 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 transmission of infection.