

Victoza®

liraglutide (rys)

Consumer Medicine Information

What is in this leaflet

- **What is in this leaflet**
- **What Victoza® is used for**
- **Before you use Victoza®**
- **How to use Victoza®**
- **While you are using Victoza®**
- **Things to be careful of**
- **Side effects**
- **After using Victoza®**
- **Product Description**
- **Further information**
- **Instructions For Use**

This leaflet answers some common questions about Victoza®.

It does not contain all the available information. It does not take the place of talking to your doctor, diabetes education nurse or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Victoza® against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Victoza® is used for

Victoza® contains the active ingredient liraglutide. This belongs to a group of medicines called 'GLP-1 receptor agonists'. Victoza® is an injection that is used once a day.

Victoza® is used to treat type 2 diabetes mellitus.

Diabetes mellitus is a condition where your pancreas does not produce enough insulin to control your blood sugar (glucose) level.

If you have type 2 diabetes mellitus your body is also not able to use insulin properly.

Victoza® helps your body to produce more insulin when your blood sugar level is high.

Victoza® is used on its own if your blood sugar is not properly controlled by diet and exercise alone and you cannot use metformin (another diabetes medicine). Victoza® is also able to be used with other medicines for diabetes when they are not enough to control your blood sugar levels.

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

Victoza® has not been studied in children and should not be used in children or adolescents under 18 years.

Victoza® is not addictive.

Victoza® is available only with a doctor's prescription.

Ask your doctor, diabetes education nurse or pharmacist if you have any questions about why Victoza® has been prescribed for you.

Before you use Victoza®

When you must not use it

Do not use Victoza® if you are allergic (hypersensitive) to liraglutide or to any of the ingredients listed in the "Ingredients" section at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- redness, swelling, rash and itching at the injection site
- rash, itching or hives on the skin
- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body.

If you are not sure whether you should start using this medicine, talk to your doctor.

Do not use this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

Before you start to use it

Tell your doctor 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. This will help your doctor to decide if the dose of the sulfonylurea or insulin needs to be changed to avoid you getting hypoglycaemia (low blood sugar).
- you have severe heart failure (disease of the heart with shortness of breath and swelling of the feet or legs due to fluid build-up)
- you have inflammatory bowel disease, such as Crohn's disease
- you have diabetic gastroparesis (a condition in which your stomach has difficulty in emptying food properly)
- you currently have or have had thyroid disease
- you are on dialysis

Drink plenty of fluids to avoid dehydration if you experience vomiting or diarrhoea when beginning treatment with Victoza®.

Dehydration can lead to kidney problems, particularly in patients who have pre-existing kidney disease.

If you notice your urine changes appearance or you produce urine less frequently, see your doctor. Contact your doctor if you have any questions or concerns.

Victoza® should not be used if you have type 1 diabetes or diabetic ketoacidosis (a complication of diabetes with high blood sugar and an increase in the effort required to breathe). Victoza® is not an insulin.

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

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are pregnant or plan to become pregnant.

Use of this medicine in pregnancy has not been studied. Victoza® should not be used during pregnancy. It is not known if Victoza® may harm your unborn child.

Tell your doctor if you are breast-feeding or plan to breast-feed.

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

If you have not told your doctor about any of the above, tell them before you use Victoza®.

Taking other medicines

Tell your doctor, pharmacist or diabetes education nurse if you are taking any other

medicines, including any that you buy without a prescription from your pharmacy, supermarket, naturopath or health food shop. In particular, tell your doctor if you are using medicines containing any of the following active ingredients:

- A sulfonylurea (such as glimepiride or glibenclamide), and/or insulin. This is because using Victoza® at the same time may cause your blood sugar level to become too low (hypoglycaemia or a "hypo").
 - When you first start using these medicines together, your doctor may tell you to lower the dose of the sulfonylurea or insulin.
 - If you are also taking a sulfonylurea and/or insulin together with Victoza®, your doctor may ask you to test your blood sugar levels to begin with. This will help your doctor to decide if the dose of the sulfonylurea and/or insulin needs to be changed.
- Warfarin or other types of medicines called 'coumarin derivatives' (anticoagulants). Your doctor may need to monitor you more closely.

Tell your doctor about any other medicines that you are taking.

This is very important. Your doctor will advise you if it is all right to keep taking them or if you should stop taking them.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while using this medicine.

How to use Victoza®

Your doctor, diabetes education nurse or pharmacist will have given you advice on how to use your medicine.

Carefully follow all the directions.

They may differ from the information contained in this leaflet.

If you do not understand the instructions, ask your doctor, diabetes education nurse or pharmacist for help.

Victoza® is supplied as a pre-filled pen containing liraglutide. The Victoza® pen can give 15 doses of 1.2 mg or 10 doses of 1.8 mg. The Victoza® pen can also give starting doses of 0.6 mg.

How much to use

Your doctor or diabetes education nurse will tell you how much of this medicine you need to use.

- 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 then be increased to 1.2 mg once a day.
- If your blood sugar level is not controlled with a dose of 1.2 mg, your doctor may increase the dose to 1.8 mg once a day.
- **Do not change your dose unless your doctor has told you to.** Any change in dose should be made cautiously and only under medical supervision.

When to use it

You can inject Victoza® at any time of day. It is preferable to inject Victoza® at about the same time each day, at a time that is most convenient for you.

Victoza® does not need to be injected at mealtimes.

How to use it

- Inject Victoza® under the skin (subcutaneous injection) as shown to you by your doctor or diabetes education nurse. **Never inject Victoza® into a vein or muscle.**
- Victoza® may be injected into the front of your waist (abdomen), the front of your thigh, or your upper arm.
- Victoza® pen is designed to be used with NovoFine® needles, up to a length of 8 mm and as thin as 32G. Needles are not included with the pen.
- Ask your doctor or diabetes education nurse which needle width (gauge) and length is best for you.
- Use a new needle for each injection and dispose of it after use.

Checking your Victoza® pen:

Victoza® should be clear and colourless, or almost colourless.

Do not use this medicine if it is thickened, coloured, or has solid bits in it.

Victoza® should not be used if it has been frozen.

Read the instructions printed later in this leaflet carefully in order to prepare and handle your Victoza® pen correctly.

How long to use it

Do not stop using Victoza® unless your doctor tells you to.

If you use too much (overdose)

If you use more Victoza® than you should, talk to your doctor straight away. You may need medical treatment. Overdose may cause nausea and vomiting.

If you forget to use it

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 are not sure what to do, talk to your doctor, diabetes education nurse or pharmacist.

While you are using Victoza®

Things you must do

Make sure all your friends, relatives, workmates or carers know that you have diabetes.

Tell your doctor if you often have hypos (low blood sugar levels).

When Victoza® is used with a sulfonylurea or with insulin, hypos can occur. The dose of your sulfonylurea or insulin may need to be reduced while you take Victoza®.

If you experience any of the symptoms of a hypo, immediately eat some sugary food or have a sugary drink, e.g. lollies, biscuits or fruit juice.

Tell your doctor, diabetes education nurse or pharmacist if you are travelling.

Ask them for a letter explaining why you are taking injecting devices with you. Each country you visit will need to see this letter, so you should take several copies.

You may not be able to get Victoza® in the country you are visiting.

Your doctor, diabetes education nurse or pharmacist can provide you with some helpful information.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are using Victoza®.

Do not use Victoza® in combination with other medicines that contain GLP-1 receptor agonists.

Things you must not do

Do not stop using your medicine unless your doctor tells you to. If you stop using it, your blood sugar levels may increase.

Do not use this medicine if you think it has been frozen or exposed to excessive heat. It will not work as well.

Do not use this medicine to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not share your pen or needles with anyone else.

Things to be careful of

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.

Side effects

Tell your doctor, diabetes education nurse or pharmacist as soon as possible if you do not feel well while you are using Victoza®.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor, diabetes education nurse or pharmacist to answer any questions you may have.

The most common side effects when using Victoza® are diarrhoea and nausea. These side effects are usually mild and normally decrease with continued use.

Tell your doctor if you notice any of the following and they worry you:

- anorexia
- decreased appetite
- headache
- vomiting (being sick)
- indigestion (dyspepsia)
- burping, wind (flatulence) or constipation
- heartburn
- painful or swollen stomach (abdomen)
- blocked or runny nose, sneezing, cough and/or sore throat (upper respiratory tract infection)
- injection site reactions (such as bruising, pain, irritation, itching and rash)
- fast heart beat
- feeling tired
- increase of pancreatic enzymes (such as lipase and amylase)
- low blood sugar (a hypo).

Hypos are more likely to occur if you are also taking a sulfonylurea or insulin. A hypo may

come on suddenly. The warning signs of a hypo can include:

- cold sweat, cool pale skin
- headache
- feeling sick
- feeling very hungry
- changes in vision
- feeling sleepy, feeling weak
- feeling nervous or anxious, shaking (tremor), fast heart beat
- feeling confused, difficulty concentrating.

Your doctor can provide you with further information about how to treat low blood sugar levels and what to do if you notice these warning signs. If you are already taking a sulfonylurea or insulin, your doctor may reduce the dose of these medicines before you start using Victoza®.

The above list includes the more common side effects of your medicine. They are usually mild and short-lived.

Tell your doctor if you experience:

- urticaria (a type of skin rash)
- malaise (feeling unwell)
- dehydration, sometimes with a decrease in kidney function
- gallstones
- inflamed gall bladder.

When initiating treatment with Victoza®, you may in some cases experience dehydration as a result of vomiting, nausea or diarrhoea. It is important to avoid dehydration by drinking plenty of fluids.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

- severe and persistent pain in the abdomen (stomach area) which might reach through to your back, as well as nausea and vomiting. These can be symptoms of acute pancreatitis. Pancreatitis can be a serious, potentially life-threatening medical condition.
- get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath.
- an allergic reaction. Some symptoms may include:
 - skin rashes over a large part of the body
 - shortness of breath, wheezing
 - swelling of the face, lips or tongue
 - fast pulse
- sweating.

This list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are rare or very rare.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may also occur in some people.

Ask your doctor, diabetes education nurse or pharmacist to answer any questions you have.

After using Victoza®

Storage

Before opening:

Keep your unopened Victoza® pens in a refrigerator (2°C to 8°C). Keep away from the cooling element. Do not freeze.

During use:

While you are using your Victoza® pen you can keep it for 1 month *either* at room temperature (not above 30°C), *or* in a refrigerator (2°C to

8°C), away from the cooling element. Do not freeze. Store the pen without a needle attached.

Discard the Victoza® pen you are using after 1 month even if there is still some medicine left in it.

The medicine in Victoza® must not be frozen, or exposed to heat or direct sunlight. When you are not using the pen, keep the pen cap on in order to protect from light. Never use Victoza® after the expiry date printed on the pen label and carton.

Never use Victoza® if the solution is not clear and colourless, or almost colourless.

Keep out of the reach of children.

Disposal

Dispose of used needles safely into a yellow plastic sharps container.

If your doctor tells you to stop using this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Victoza® is supplied as a clear, colourless, or almost colourless solution for injection in a pre-filled pen. One mL solution for injection contains 6 mg liraglutide. One pre-filled pen contains 18 mg liraglutide.

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.

Ingredients

Victoza® contains liraglutide (rys) 6 mg/mL as the active ingredient. The abbreviation “rys” indicates the method of genetic engineering used to manufacture liraglutide.

Victoza® also contains the following inactive ingredients:

- dibasic sodium phosphate dihydrate
- propylene glycol
- phenol
- hydrochloric acid
- sodium hydroxide
- water for injections.

Sponsor

Victoza® is supplied in Australia by:

Novo Nordisk Pharmaceuticals Pty. Ltd.

Level 3

21 Solent Circuit

Baulkham Hills NSW 2153

This leaflet was prepared on 12 January 2018.

Australian Registration Number:

AUST R 153980

Victoza®, NovoFine® and NovoCare® are trademarks owned by Novo Nordisk A/S.

© 2018

Novo Nordisk A/S

Further information

For further information call the NovoCare® Customer Care Centre on 1800 668 626.

www.novonordisk.com.au

You can also get more information about diabetes from Diabetes Australia:

freecall helpline 1300 136 588

www.diabetesaustralia.com.au

The ‘Product Information’ document is available from the following

websites: www.novonordisk.com.au

<https://www.ebs.tga.gov.au/>

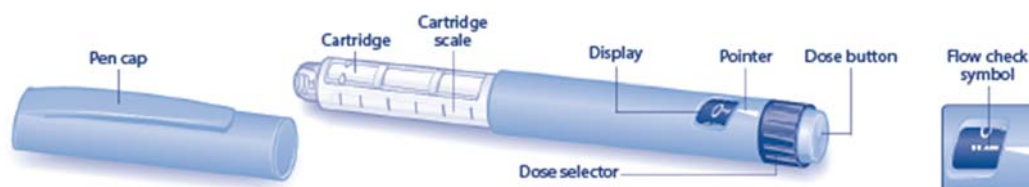
Instructions For Use

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

Your Victoza® pen contains 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 injection needles up to a length of 8 mm and as thin as 32G. Needles are not included in the pack.

Victoza® Pen



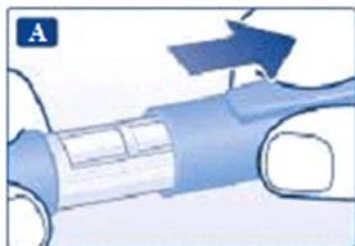
Needle (example)



Prepare your Victoza® pen

Check the name and coloured label of your pen to make sure that it contains Victoza®. 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 dispose of it.



- Always use a new needle for each injection. This reduces the risk of contamination, infection, leakage of Victoza®, 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 damage the pen.

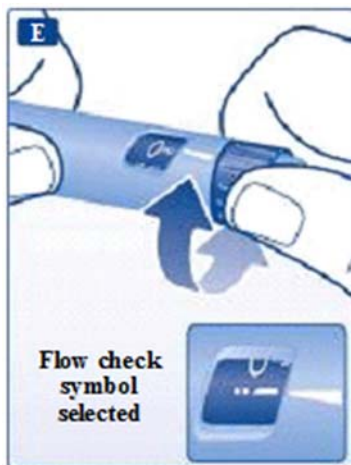
Important information

- Do not share your Victoza® pen or needles with anyone else.
- Keep your Victoza® pen out of 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.

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 Victoza® 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 Victoza®, change the needle and repeat steps E to G once more.

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

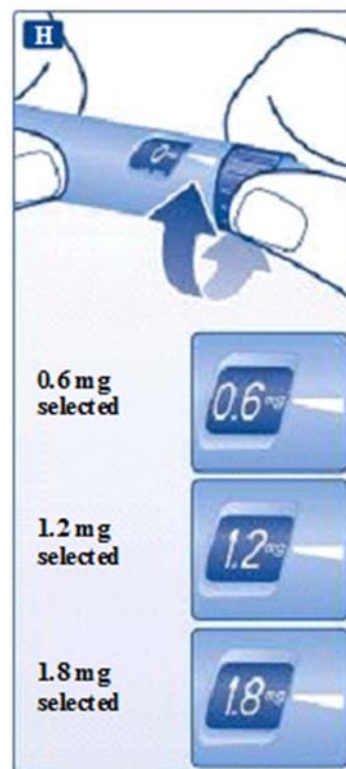


- If you have dropped your pen against a hard surface or suspect that something is wrong with it, always put on a new disposable needle and check the flow before you inject.

Select your dose

Always check that the pointer lines up with 0 mg.

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



If you select an incorrect 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 Victoza® may come out.

If the dose selector stops before your required dose lines up with the pointer, there is not enough Victoza® 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. Then prepare a new pen for injection and inject the remaining number of mg to complete your dose.

- You may only divide your dose between your current pen and a new pen if trained or advised by your doctor or diabetes education nurse. Use a calculator to plan the doses. If you divide the dose incorrectly, you may inject too much or too little Victoza®.

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 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 clicks to select your dose. Do not use the cartridge scale to measure how much Victoza® 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 diabetes education nurse. Then follow the instructions below:

I. Press the dose button to inject until 0 mg lines up with the pointer.

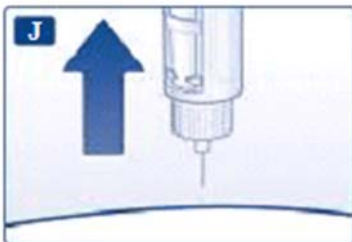
Be careful to only push the dose button when injecting. Turning the dose selector will not inject Victoza®. Be careful not to touch the display with your other fingers or press the dose selector sideways when you inject. This is because it may block the injection.

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.

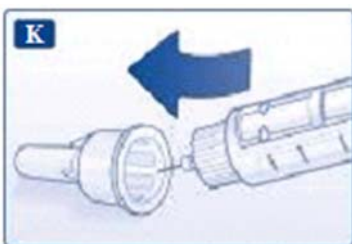


J. Pull out the needle.

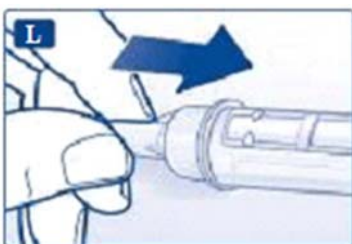
After that, you may see a drop of Victoza® at the needle tip. This is normal and does not affect your dose.



K. Guide the needle tip into the outer needle cap without touching the needle or 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. Dispose of pens and needles into a yellow plastic sharps container.

- **Always remove the needle after each injection**, and store your Victoza® pen without a needle attached.
- This reduces the risk of contamination, infection, leakage of Victoza®, blocked needles and inaccurate dosing.
- Healthcare professionals, relatives and other carers should follow general precautionary measures for removal and disposal of needles, to avoid hurting themselves with the needles.