

PART III: CONSUMER INFORMATION

 **VICTOZA®**
(liraglutide)

This leaflet is part III of a three-part "Product Monograph" published when VICTOZA® was approved for sale in Canada and is designed specifically for Consumers. This leaflet is a summary and will not tell you everything about VICTOZA®. Contact your doctor or pharmacist if you have any questions about the drug.

Please read this information carefully before you start to take your medicine, even if you have just refilled your prescription. Some of the information may have changed.

Remember that your physician has prescribed this medicine only for you. Never give it to anyone else

ABOUT THIS MEDICATION

What the medication is used for:

VICTOZA® is used in combination metformin or with metformin and a sulfonylurea to improve blood sugar levels in adult patients with type 2 diabetes.

VICTOZA® should not be used in type 1 diabetes (formerly known as insulin-dependent diabetes mellitus or IDDM).

What it does:

VICTOZA® belongs to a class of medicines called GLP-1 analog. VICTOZA® (liraglutide) 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.

When it should not be used:

Do not use VICTOZA® if:

- you or a member of your family have 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

What the medicinal ingredient is:

liraglutide

What the important nonmedicinal ingredients are:

Disodium phosphate dihydrate, propylene glycol, phenol and

water for injections.

What dosage forms it comes in:

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

WARNINGS AND PRECAUTIONS

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.

BEFORE you use VICTOZA® talk to your doctor or pharmacist 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)
- You have type 1 diabetes
- You have ever had diabetic ketoacidosis (increased ketones in the blood or urine)
- You have ever had an allergic reaction to VICTOZA®
- You have a high heart rate (fast pulse)
- You have a condition called heart block
- You 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)
- You have kidney problems
- You have liver problems
- You have gastrointestinal (digestive) problems
- You have ever had pancreatitis
- You are breast-feeding or plan to breast-feed.
- You are pregnant or plan to become pregnant

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.

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 **SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM.**

VICTOZA® is not recommended for use in children under 18 years of age.

INTERACTIONS WITH THIS MEDICATION

Tell your physician, diabetes nurse or pharmacist if you are taking or have recently taken any other medicines. This includes prescription and non-prescription medicines and herbal supplements.

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

- Insulin – using VICTOZA® is not recommended if you are using insulin.
- 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.
- If you are not sure if the medicines you are taking contain a sulfonylurea, ask your doctor, diabetes nurse or pharmacist.

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

PROPER USE OF THIS MEDICATION

Take VICTOZA® exactly as your physician has prescribed.

Usual dose:

VICTOZA® can be taken at any time of 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 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.

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.

Overdose:

In case of drug overdose, contact a health care practitioner, 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) or become sick (vomit).

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.

Administering 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 or diabetes nurse 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. You can give yourself the injection at any time of the day. **See Instructions for Use.**

SIDE EFFECTS AND WHAT TO DO ABOUT THEM

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

Very common (affect 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.
- Headache.
- 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.

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 physician, diabetes nurse or pharmacist.

- **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 the medicine from light.
- Protect VICTOZA® from high temperatures and sunlight.
- 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.

SERIOUS SIDE EFFECTS, HOW OFTEN THEY HAPPEN AND WHAT TO DO ABOUT THEM

Symptom / effect		Talk with your doctor or pharmacist		Stop taking drug and call your doctor or pharmacist
		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		T	T
Rare	Pancreatitis / persistent, severe abdominal pain with or without vomiting		T	
Rare	Severe hypoglycemia / disorientation, loss of consciousness, and seizures		T	
Very Rare	Thyroid tumour / lump in the neck, difficulty in swallowing difficulty in breathing or persistent hoarseness		T	

This is not a complete list of side effects. For any unexpected effects while taking VICTOZA®, contact your doctor or pharmacist-

HOW TO STORE IT

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 to 8°C) away from the freezer compartment. Do not freeze it.

REPORTING SUSPECTED SIDE EFFECTS

You can report any suspected adverse reactions associated with the use of health products to the Canada Vigilance Program by one of the following 3 ways:

- Report online at www.healthcanada.gc.ca/medeffect
- Call toll-free at 1-866-234-2345
- Complete a Canada Vigilance Reporting Form and:
 - Fax toll-free to 1-866-678-6789, or
 - Mail to: Canada Vigilance Program

Health Canada
Postal Locator 0701D
Ottawa, ON K1A 0K9

Postage paid labels, Canada Vigilance Reporting Form and the adverse reaction reporting guidelines are available on the MedEffect™ Canada Web site at www.healthcanada.gc.ca/medeffect.

NOTE: Should you require information related to the management of side effects, contact your health professional. The Canada Vigilance Program does not provide medical advice.

MORE INFORMATION

This document plus the full product monograph, prepared for health professionals can be found at: <http://www.novonordisk.ca> or by contacting the sponsor, Novo Nordisk Canada Inc., at 1-800-465-4334.

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