

Medication Guide
Victoza® (VIC-tow-za)
(liraglutide [rDNA origin] injection)
solution, for subcutaneous use

Read this Medication Guide before you start using Victoza and each time you get a refill. There may be new information. This information does not take the place of talking to your healthcare provider about your medical condition or your treatment.

What is the most important information I should know about Victoza?

Victoza may cause serious side effects, including:

- **Possible thyroid tumors, including cancer.** Tell your healthcare provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer. In studies with rats and mice, Victoza and medicines that work like Victoza caused thyroid tumors, including thyroid cancer. It is not known if Victoza will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people.
- Do not use Victoza if you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC), or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

What is Victoza?

Victoza is an injectable prescription medicine that may improve blood sugar (glucose) in adults with type 2 diabetes mellitus, and should be used along with diet and exercise.

- Victoza is not recommended as the first choice of medicine for treating diabetes.
- It is not known if Victoza can be used in people who have had pancreatitis.
- Victoza is not a substitute for insulin and is not for use in people with type 1 diabetes or people with diabetic ketoacidosis.
- It is not known if Victoza can be used with mealtime insulin.
- It is not known if Victoza is safe and effective for use in children.

Who should not use Victoza?

Do not use Victoza if:

- you or any of your family have ever had a type of thyroid cancer called medullary thyroid carcinoma (MTC) or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- you are allergic to liraglutide or any of the ingredients in Victoza. See the end of this Medication Guide for a complete list of ingredients in Victoza.

What should I tell my healthcare provider before using Victoza?

Before using Victoza, tell your healthcare provider if you:

- have or have had problems with your pancreas, kidneys, or liver
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food
- have any other medical conditions
- are pregnant or plan to become pregnant. It is not known if Victoza will harm your unborn baby. Tell your healthcare provider if you become pregnant while using Victoza.
- are breastfeeding or plan to breastfeed. It is not known if Victoza passes into your breast milk. You should not use Victoza while breastfeeding without first talking with your healthcare provider.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Victoza may affect the way some medicines work and some medicines may affect the way Victoza works.

Before using Victoza, talk to your healthcare provider about low blood sugar and how to manage it. Tell your healthcare provider if you are taking other medicines to treat diabetes, including insulin or sulfonylureas.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I use Victoza?

- Read the **Instructions for Use** that comes with Victoza.
- Use Victoza exactly as your healthcare provider tells you to.

- **Your healthcare provider should show you how to use Victoza before you use it for the first time.**
- Victoza is injected under the skin (subcutaneously) of your stomach (abdomen), thigh, or upper arm. **Do not** inject Victoza into a muscle (intramuscularly) or vein (intravenously).
- **Use Victoza 1 time each day, at any time of the day.**
- If you miss a dose of Victoza, take the missed dose at the next scheduled dose. **Do not** take 2 doses of Victoza at the same time.
- Victoza may be taken with or without food.
- **Do not** mix insulin and Victoza together in the same injection.
- You may give an injection of Victoza and insulin in the same body area (such as your stomach area), but not right next to each other.
- Change (rotate) your injection site with each injection. **Do not** use the same site for each injection.
- **Do not share your Victoza pen with other people, even if the needle has been changed.** You may give other people a serious infection, or get a serious infection from them.

Your dose of Victoza and other diabetes medicines may need to change because of:

- change in level of physical activity or exercise, weight gain or loss, increased stress, illness, change in diet, or because of other medicines you take.

What are the possible side effects of Victoza?

Victoza may cause serious side effects, including:

- **See “What is the most important information I should know about Victoza?”**
- **inflammation of your pancreas (pancreatitis).** Stop using Victoza and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back.
- **low blood sugar (hypoglycemia).** Your risk for getting low blood sugar may be higher if you use Victoza with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin.
Signs and symptoms of low blood sugar may include:
 - dizziness or light-headedness
 - blurred vision
 - anxiety, irritability, or mood changes
 - sweating
 - slurred speech
 - hunger
 - confusion or drowsiness
 - shakiness
 - weakness
 - headache
 - fast heartbeat
 - feeling jittery
- **kidney problems (kidney failure).** In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems to get worse.
- **serious allergic reactions.** Stop using Victoza and get medical help right away, if you have any symptoms of a serious allergic reaction including itching, rash, or difficulty breathing.

The most common side effects of Victoza may include headache, nausea, diarrhea, vomiting, anti-liraglutide antibodies in your blood.

Talk to your healthcare provider about any side effect that bothers you or does not go away. These are not all the possible side effects of Victoza.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

General information about the safe and effective use of Victoza.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use Victoza for a condition for which it was not prescribed. Do not give Victoza to other people, even if they have the same symptoms that you have. It may harm them.

This Medication Guide summarizes the most important information about Victoza. If you would like more information, talk with your healthcare provider. You can ask your pharmacist or healthcare provider for information about Victoza that is written for health professionals.

For more information, go to victoza.com or call 1-877-484-2869.

What are the ingredients in Victoza?

Active Ingredient: liraglutide

Inactive Ingredients: disodium phosphate dihydrate, propylene glycol, phenol and water for injection

This Medication Guide has been approved by the U.S. Food and Drug Administration.

Manufactured by: Novo Nordisk A/S, DK-2880 Bagsvaerd, Denmark

Victoza® is a registered trademark of Novo Nordisk A/S. Victoza® is covered by US Patent Nos. 6,268,343,

6,458,924, 7,235,627, 8,114,833 and other patents pending. Victoza[®] pen is covered by US Patent Nos. 6,004,297, RE 43,834, RE 41,956 and other patents pending.

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