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Source : U.S. National Library of Medicine

URL of this page: <https://medlineplus.gov/druginfo/meds/a611003.html>

Liraglutide Injection

pronounced as (lir" a gloo' tide)

IMPORTANT WARNING:

Liraglutide injection may increase the risk that you will develop tumors of the thyroid gland, including medullary thyroid carcinoma (MTC; a type of thyroid cancer). Laboratory animals who were given liraglutide developed tumors, but it is not known if this medication increases the risk of tumors in humans. Tell your doctor if you or anyone in your family has or has ever had MTC or Multiple Endocrine Neoplasia syndrome type 2 (MEN 2; condition that causes tumors in more than one gland in the body). If so, your doctor will probably tell you not to use liraglutide injection. If you experience any of the following symptoms, call your doctor immediately: lump or swelling in the neck; hoarseness; difficulty swallowing; or shortness of breath.

Keep all appointments with your doctor and the laboratory. Your doctor may order certain tests to check your body's response to liraglutide injection.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with liraglutide injection and each time you refill your prescription. Read the information carefully and ask your doctor or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm> [<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>]) or the manufacturer's website to obtain the Medication Guide.

Talk to your doctor about the risks of using liraglutide injection.

Why is this medication prescribed?

Liraglutide injection (Victoza) is used with a diet and exercise program to control blood sugar levels in adults and children 10 years of age and older with type 2 diabetes (condition in which the body does not use insulin normally and therefore cannot control the amount of sugar in the blood) when other medications did not control levels well enough. Liraglutide injection (Victoza) is also used to reduce the risk of a heart attack, stroke, or death in adults with type 2 diabetes mellitus and heart and blood vessel disease. Liraglutide injection (Victoza) is not used to treat type 1 diabetes (condition in which the body

does not produce insulin and therefore cannot control the amount of sugar in the blood) or diabetic ketoacidosis (a serious condition that may develop if high blood sugar is not treated) in adults. Liraglutide injection (Saxenda) is used along with a reduced calorie diet and exercise plan to help certain adults and children 12 years of age and older who weigh 132 pounds (60 kg) or more and who are obese or who are overweight and have weight-related medical problems to lose weight and to keep from gaining back that weight. Liraglutide injection (Saxenda) is not used to treat type 2 diabetes. Liraglutide injection is in a class of medications called incretin mimetics. It works by helping the pancreas to release the right amount of insulin when blood sugar levels are high. Insulin helps move sugar from the blood into other body tissues where it is used for energy. Liraglutide injection also slows the emptying of the stomach and may decrease appetite and cause weight loss.

Over time, people who have diabetes and high blood sugar can develop serious or life-threatening complications, including heart disease, stroke, kidney problems, nerve damage, and eye problems. Using medication(s), making lifestyle changes (e.g., diet, exercise, quitting smoking), and regularly checking your blood sugar may help to manage your diabetes and improve your health. This therapy may also decrease your chances of having a heart attack, stroke, or other diabetes-related complications such as kidney failure, nerve damage (numb, cold legs or feet; decreased sexual ability in men and women), eye problems, including changes or loss of vision, or gum disease. Your doctor and other healthcare providers will talk to you about the best way to manage your diabetes.

How should this medicine be used?

Liraglutide injection comes as a solution (liquid) in a prefilled dosing pen to inject subcutaneously (under the skin) in your stomach, thigh, or upper arm. It is usually injected once a day with or without food. Use liraglutide injection at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Use liraglutide injection exactly as directed. Do not use more or less of it or use it more often than prescribed by your doctor.

Your doctor will probably start you on a low dose of liraglutide injection and increase your dose after 1 week.

Liraglutide injection (Victoza) controls diabetes but does not cure it. Continue to use liraglutide injection even if you feel well. Do not stop using liraglutide injection without talking to your doctor.

If you are an adult using liraglutide injection (Saxenda) for weight loss and you do not lose a certain amount of weight after 16 weeks of treatment, it is not likely that you will benefit from using this medication. If you are a child 12 years of age and older using liraglutide injection (Saxenda) and you do not lose a certain amount of weight after 12 weeks on the maintenance dose, it is not likely that you will benefit from using this medication. Your doctor may tell you to stop using liraglutide injection (Saxenda) if you do not lose enough weight during the first weeks of your treatment.

You will need to buy needles separately. Ask your doctor or pharmacist what type of needles you will need to inject your medication. Be sure to read and understand the manufacturer's instructions for injecting liraglutide using the pen. Also make sure you know how and when to set up a new pen, and what to do if you drop your pen. If you are blind or have poor eyesight and cannot read the dose

counter on the pen, do not use this pen without help. Ask your doctor or pharmacist to show you how to use the pen. Follow the directions carefully.

Always look at your liraglutide solution before you inject it. It should be clear, colorless, and free of particles. Do not use liraglutide if it is colored, cloudy, thickened, or contains solid particles, or if the expiration date on the bottle has passed.

Never reuse needles and never share needles or pens. Always remove the needle right after you inject your dose. Dispose of needles in a puncture-resistant container. Ask your doctor or pharmacist how to dispose of the puncture resistant container.

Ask your pharmacist or doctor for a copy of the manufacturer's information for the patient.

Other uses for this medicine

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

What special precautions should I follow?

Before using liraglutide injection,

- tell your doctor and pharmacist if you are allergic to liraglutide, any other medications, or any of the ingredients in liraglutide injection. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what other prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. It is especially important to tell your doctor about all the medications you take by mouth because liraglutide may change the way your body absorbs these medications. Also tell your doctor about other incretin mimetics such as albiglutide (Tanzeum; no longer available in the US) dulaglutide (Trulicity), exenatide (Bydureon, Byetta), lixisenatide (Adlyxin, in Soliqua), or semaglutide (Ozempic); insulin; or oral medications for diabetes, such as sulfonylureas, including chlorpropamide, glimepiride (Amaryl, in Duetact), glipizide (Glucotrol), glyburide (DiaBeta, Glynase), tolazamide, and tolbutamide. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you drink or have ever drunk large amounts of alcohol, if you have or have ever had depression, thought about or attempted suicide, changes in behavior, pancreatitis (inflammation of the pancreas); severe stomach problems, including gastroparesis (slowed movement of food from the stomach to the small intestine), problems digesting food; a high level of triglycerides (fats) in the blood; gallstones (solid deposits that form in the gallbladder); or gallbladder, kidney or liver disease. Also tell your doctor if you have recently had diarrhea, nausea, or vomiting or if you cannot drink liquids by mouth, which may cause dehydration (loss of a large amount of body fluids).
- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you are pregnant you should not use liraglutide injection (Saxenda) for weight loss. If you become pregnant while using liraglutide injection (Victoza), call your doctor.
- ask your doctor what to do if you get sick, develop an infection or fever, experience unusual stress, or are injured. These conditions can affect your blood sugar and the amount of liraglutide you may need.

What special dietary instructions should I follow?

Be sure to follow all exercise and dietary recommendations made by your doctor or dietitian.

What should I do if I forget a dose?

Inject the missed dose as soon as you remember it. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not inject a double dose to make up for a missed one. If you forget to use liraglutide injection for 3 or more days, call your doctor.

What side effects can this medication cause?

This medication may cause changes in your blood sugar. You should know the symptoms of low and high blood sugar and what to do if you have these symptoms.

Liraglutide injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- headache
- constipation
- heartburn
- runny nose, sneezing, or cough
- tiredness
- difficulty urinating or pain or burning on urination
- injection site rash or redness

Some side effects can be serious. If you experience either of these symptoms or those listed in the IMPORTANT WARNING or SPECIAL PRECAUTIONS sections, stop using liraglutide injection and call your doctor immediately:

- ongoing pain that begins in the upper left or middle of the stomach but may spread to the back
- new or worsening depression
- thinking about harming or killing yourself
- unusual changes in mood or behavior
- vomiting
- nausea
- diarrhea
- clay-colored stools
- yellow eyes or skin
- heart pounding
- fainting or feeling dizzy
- swelling of the eyes, face, mouth, tongue, or throat
- rash

- itching
- difficulty breathing or swallowing

Liraglutide injection may cause other side effects. Call your doctor if you have any unusual problems while using this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch> [<http://www.fda.gov/Safety/MedWatch>]) or by phone (1-800-332-1088).

What should I know about storage and disposal of this medication?

Keep this medication in the container it came in and out of reach of children. Store it away from light and heat. Store unused liraglutide pens in the refrigerator (36°F to 46°F [2°C to 8°C]) but do not place them near the refrigerator cooling element. Once a liraglutide pen is in use, store it at room temperature (59°F to 86°F [15°C to 30°C]) or in the refrigerator. Do not freeze. Do not use liraglutide if it has been frozen or exposed to temperatures above 86°F (30°C). Keep the cap on the liraglutide pen when it is not in use.

When traveling, be sure to keep liraglutide pens dry and at a temperature between 59°F to 86°F (15°C to 30°C).

Make a note of the date you first use a liraglutide pen, and dispose of the pen after 30 days, even if there is some solution left in the pen.

It is important to keep all medication out of sight and reach of children as many containers (such as weekly pill minders and those for eye drops, creams, patches, and inhalers) are not child-resistant and young children can open them easily. To protect young children from poisoning, always lock safety caps and immediately place the medication in a safe location – one that is up and away and out of their sight and reach. <http://www.upandaway.org> [<http://www.upandaway.org>]

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p> [<http://goo.gl/c4Rm4p>]) for more information if you do not have access to a take-back program.

In case of emergency/overdose

In case of overdose, call the poison control helpline at 1-800-222-1222. Information is also available online at <https://www.poisonhelp.org/help> [<https://www.poisonhelp.org/help>]. If the victim has collapsed, had a seizure, has trouble breathing, or can't be awakened, immediately call emergency services at 911.

Symptoms of overdose may include the following:

- severe nausea
- severe vomiting

What other information should I know?

If you are using liraglutide (Victoza) injection for treatment of diabetes, your blood sugar and glycosylated hemoglobin (HbA1c) should be checked regularly to determine your response to this medication. Your doctor will also tell you how to check your response to liraglutide injection by measuring your blood sugar levels at home. Follow these directions carefully.

If you are using liraglutide (Saxenda) injection for weight management, your heart rate and weight will be checked regularly during treatment.

Do not let anyone else use your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

Brand names

- Saxenda[®]
- Victoza[®]
- Xultophy[®] (as a combination product containing Insulin Degludec and Liraglutide)

Last Revised - 02/15/2021

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