NEW
VICTOZA®
liraglutide (rDNA origin) injection

Indications and Usage

- Victoza® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
- Because of the uncertain relevance of the rodent thyroid C-cell tumor findings to humans, prescribe Victoza® only to patients for whom the potential benefits are considered to outweigh the potential risk. Victoza® is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise.
- In clinical trials of Victoza®, there were more cases of pancreatitis with Victoza® than with comparators. Victoza® has not been studied sufficiently in patients with a history of pancreatitis to determine whether these patients are at increased risk for pancreatitis while using Victoza®. Use with caution in patients with a history of pancreatitis.
- Victoza® is not a substitute for insulin. Victoza® should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis, as it would not be effective in these settings.
- The concurrent use of Victoza® and insulin has not been studied.

Additional Information

- Victoza® is a glucagon-like peptide-1 (GLP-1) receptor agonist.
- Victoza® can be used as monotherapy or as combination therapy.
- The 0.6 mg dose is a starting dose intended to reduce gastrointestinal symptoms during initial titration, and is not effective for glycemic control. After one week, the dose should be increased to 1.2 mg. If the 1.2mg dose does not result in acceptable glycemic control, the dose can be increased to 1.8 mg.
- Needles are not included with the pen. A prescription for needles may be required in some states. Be sure to dispense needles with Victoza® prescriptions. Victoza® pens are designed for use with disposable needles as thin as the NovoFine® 32G Tip needle.
- The TWO pen package should be dispensed for patients on the 1.2 mg dose for 30 days of therapy. The THREE pen pack should be dispensed for patients on the 1.8 mg dose for 30 days of therapy.

Important Safety Information:

Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors at clinically relevant exposures in both genders of rats and mice. It is unknown whether Victoza® causes thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as human relevance could not be ruled out by clinical or nonclinical studies. Victoza® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Based on the findings in rodents, monitoring with serum calcitonin or thyroid ultrasound was performed during clinical trials, but this may have increased the number of unnecessary thyroid surgeries. It is unknown whether monitoring with serum calcitonin or thyroid ultrasound will mitigate human risk of thyroid C-cell tumors. Patients should be counseled regarding the risk and symptoms of thyroid tumors.

In clinical trials, there were more cases of pancreatitis among Victoza®-treated patients than among comparator-treated patients. If pancreatitis is suspected, Victoza® should be discontinued. Victoza® should not be re-initiated if pancreatitis is confirmed. Use with caution in patients with a history of pancreatitis.

When Victoza® is used with an insulin secretagogue (e.g. a sulfonylurea) serious hypoglycemia can occur. Consider lowering the dose of the insulin secretagogue to reduce the risk of hypoglycemia.

There have been no studies establishing conclusive evidence of macrovascular risk reduction with Victoza® or any other antidiabetic drug.

The most common adverse reactions, reported in ≥5% of patients treated with Victoza® and more commonly than in patients treated with placebo, are headache, nausea, diarrhea and anti-liraglutide antibody formation. Immunogenicity related events, including urticaria, were more common among Victoza®-treated patients (0.8%) than among comparator treated patients (0.4%) in clinical trials.

In a 52-week monotherapy study (n=745), the adverse reactions reported in ≥5% of patients treated with Victoza® or ≥5% of patients treated with glimepiride were nausea (28.4% vs 8.5%), diarrhea (17.1% vs 8.9%), vomiting (10.9% vs 3.6%), constipation (9.9% vs 4.8%), upper respiratory tract infection (9.5% vs 5.6%), headache (9.1 vs 9.3%), influenza (7.4% vs 3.6%), urinary tract infection (6.0% vs 4.0%), dizziness (5.8% vs 5.2%), sinusitis (5.6% vs 6.0%), nasopharyngitis (5.2% vs 5.2%), back pain (5.0% vs 4.4%), and hypertension (3.0% vs 6.0%).

Victoza® has not been studied in type 2 diabetes patients below 18 years of age and is not recommended for use in pediatric patients.

Victoza® should be used with caution in patients with renal impairment and in patients with hepatic impairment.

Please see accompanying Prescribing Information.

Frequently Asked Questions:

1 **What are the most common side effects of Victoza®?**

The most common side effects with Victoza® include headache, nausea, and diarrhea. Nausea is most common when first starting Victoza®, but decreases over time in most people as their body gets used to the medicine. Please refer to the Medication Guide for further information.

2 **How often is Victoza® taken?**

Victoza® is taken once a day, with or without food at any time during the day. It is recommended to take Victoza® at the same time of day.

3 **How is Victoza® stored before and after first use?**

Prior to first use	After first use	
Refrigerated 36°F to 46°F (2°C to 8°C)	Room Temperature 59°F to 86°F (15°C to 30°C)	Refrigerated 36°F to 46°F (2°C to 8°C)
Until expiration date	30 days	

4 **Is hypoglycemia a side effect?**

Your risk for getting hypoglycemia, or low blood sugar, is higher if you take Victoza® with another medicine that can cause low blood sugar, such as a sulfonylurea. The dose of your sulfonylurea medicine may need to be lowered while taking Victoza®. Please refer to the Medication Guide for further information.

To speak with a Victoza® Care Specialist, call 1-877-4-VICTOZA (1-877-484-2869) Monday–Friday, 8:00AM–7:00PM EST, or visit VICTOZA.com for more information.