

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use VICTOZA safely and effectively. See full prescribing information for VICTOZA.

VICTOZA® (liraglutide) injection, for subcutaneous use
Initial U.S. Approval: 2010

WARNING: RISK OF THYROID C-CELL TUMORS

See full prescribing information for complete boxed warning.

- Liraglutide causes 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 the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined (5.1, 13.1).
- VICTOZA is contraindicated in patients with a personal or family history of MTC or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2). Counsel patients regarding the potential risk of MTC and the symptoms of thyroid tumors (4, 5.1).

RECENT MAJOR CHANGES

Dosage and Administration (2.1)-----06/2022
Warnings and Precautions (5.7)-----06/2022

INDICATIONS AND USAGE

VICTOZA is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated:

- as an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus (1).
- to reduce the risk of major adverse cardiovascular events in adults with type 2 diabetes mellitus and established cardiovascular disease (1).

Limitations of Use:

- Not for treatment of type 1 diabetes mellitus.
- Should not be coadministered with other liraglutide-containing products.

DOSAGE AND ADMINISTRATION

- Inspect visually prior to each injection. Only use if solution is clear, colorless, and contains no particles (2.1).
- Inject VICTOZA subcutaneously once-daily at any time of day, independently of meals, in the abdomen, thigh or upper arm (2.1).
- When using VICTOZA with insulin, administer as separate injections. Never mix. (2.1).
- Adult Dosage: Initiate at 0.6 mg daily for one week then increase to 1.2 mg daily. If additional glycemic control is required, increase the dose to 1.8 mg daily after one week of treatment with the 1.2 mg daily dose (2.2).
- Pediatric Dosage: Initiate at 0.6 mg daily for at least one week. If additional glycemic control is required increase the dose to 1.2 mg daily and if additional glycemic control is still required, increase the dose to 1.8 mg daily after at least one week of treatment with the 1.2 mg daily dose (2.3).

DOSAGE FORMS AND STRENGTHS

Injection: 6 mg/mL solution in a pre-filled, single-patient-use pen that delivers doses of 0.6 mg, 1.2 mg, or 1.8 mg (3).

CONTRAINDICATIONS

VICTOZA is contraindicated in patients with a personal or family history of medullary thyroid carcinoma or in patients with Multiple Endocrine Neoplasia syndrome type 2 (4).

VICTOZA is contraindicated in patients with a serious hypersensitivity reaction to liraglutide or any of the excipients in VICTOZA (4).

WARNINGS AND PRECAUTIONS

- **Thyroid C-cell Tumors:** See Boxed Warning (5.1).
- **Pancreatitis:** Postmarketing reports, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis. Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed (5.2).
- **Never share a VICTOZA pen** between patients, even if the needle is changed (5.3).
- **Hypoglycemia:** Adult patients taking an insulin secretagogue or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia. In pediatric patients 10 years of age and older, the risk of hypoglycemia was higher with VICTOZA regardless of insulin and/or metformin use. Reduction in the dose of insulin secretagogues or insulin may be necessary (5.4).
- **Renal Impairment:** Postmarketing, usually in association with nausea, vomiting, diarrhea, or dehydration which may sometimes require hemodialysis. Use caution when initiating or escalating doses of VICTOZA in patients with renal impairment (5.5).
- **Hypersensitivity:** Postmarketing reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema). Discontinue VICTOZA and promptly seek medical advice (5.6).
- **Acute Gallbladder Disease:** If cholelithiasis or cholecystitis are suspected, gallbladder studies are indicated (5.7)

ADVERSE REACTIONS

- The most common adverse reactions, reported in $\geq 5\%$ of patients treated with VICTOZA are: nausea, diarrhea, vomiting, decreased appetite, dyspepsia, constipation (6.1).
- Immunogenicity-related events, including urticaria, were more common among VICTOZA-treated patients (0.8%) than among comparator-treated patients (0.4%) in clinical trials (6.2).

To report SUSPECTED ADVERSE REACTIONS, contact Novo Nordisk Inc. at 1-877-484-2869 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

Oral Medications: VICTOZA delays gastric emptying and may impact absorption of concomitantly administered oral medications (7).
Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin: when initiating, consider reducing the dose of concomitantly administered insulin secretagogues (such as sulfonylureas) or insulin to reduce the risk of hypoglycemia (7).

USE IN SPECIFIC POPULATIONS

- **Pregnancy:** VICTOZA should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus (8.1).

See 17 for PATIENT COUNSELING INFORMATION and FDA-Approved Medication Guide.

Revised:06/2022

FULL PRESCRIBING INFORMATION: CONTENTS*

WARNING: RISK OF THYROID C-CELL TUMORS

1	INDICATIONS AND USAGE
2	DOSAGE AND ADMINISTRATION
2.1	Important Dosing and Administration Instructions
2.2	Adult Dosage
2.3	Pediatric Dosage
3	DOSAGE FORMS AND STRENGTHS
4	CONTRAINDICATIONS
5	WARNINGS AND PRECAUTIONS
5.1	Risk of Thyroid C-cell Tumors
5.2	Pancreatitis
5.3	Never Share a VICTOZA Pen Between Patients
5.4	Hypoglycemia
5.5	Renal Impairment
5.6	Hypersensitivity Reactions
5.7	Acute Gallbladder Disease
6	ADVERSE REACTIONS
6.1	Clinical Trials Experience
6.2	Immunogenicity
6.3	Post-Marketing Experience
7	DRUG INTERACTIONS
7.1	Oral Medications
7.2	Concomitant Use with an Insulin Secretagogue (e.g., Sulfonylurea) or with Insulin
8	USE IN SPECIFIC POPULATIONS
8.1	Pregnancy
8.2	Lactation
8.4	Pediatric Use
8.5	Geriatric Use
8.6	Renal Impairment
8.7	Hepatic Impairment
8.8	Gastroparesis

10	OVERDOSAGE
11	DESCRIPTION
12	CLINICAL PHARMACOLOGY
12.1	Mechanism of Action
12.2	Pharmacodynamics
12.3	Pharmacokinetics
13	NONCLINICAL TOXICOLOGY
13.1	Carcinogenesis, Mutagenesis, Impairment of Fertility
14	CLINICAL STUDIES
14.1	Glycemic Control Trials in Adults with Type 2 Diabetes Mellitus
14.2	Glycemic Control Trial in Pediatric Patients 10 Years of Age and Older with Type 2 Diabetes Mellitus
14.3	Cardiovascular Outcomes Trial in Patients with Type 2 Diabetes Mellitus and Atherosclerotic Cardiovascular Disease
16	HOW SUPPLIED/STORAGE AND HANDLING
16.1	How Supplied
16.2	Recommended Storage
17	PATIENT COUNSELING INFORMATION

*Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

WARNING: RISK OF THYROID C-CELL TUMORS

- **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 the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined [see Warnings and Precautions (5.1) and Nonclinical Toxicology (13.1)].**
- **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). Counsel patients regarding the potential risk for MTC with the use of VICTOZA and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with VICTOZA [see Contraindications (4) and Warnings and Precautions (5.1)].**

1 INDICATIONS AND USAGE

VICTOZA is indicated:

- as an adjunct to diet and exercise to improve glycemic control in patients 10 years and older with type 2 diabetes mellitus,
- to reduce the risk of major adverse cardiovascular events (cardiovascular death, non-fatal myocardial infarction, or non-fatal stroke) in adults with type 2 diabetes mellitus and established cardiovascular disease [see Clinical Studies (14.3)].

Limitations of Use:

VICTOZA should not be used in patients with type 1 diabetes mellitus.

VICTOZA contains liraglutide and should not be coadministered with other liraglutide-containing products.

2 DOSAGE AND ADMINISTRATION

2.1 Important Dosing and Administration Instructions

- Inspect visually prior to each injection. Only use if solution is clear, colorless, and contains no particles.
- Inject VICTOZA subcutaneously once-daily at any time of day, independently of meals.
- Inject VICTOZA subcutaneously in the abdomen, thigh or upper arm. No dose adjustment is needed if changing the injection site and/or timing.
- Rotate injection sites within the same region in order to reduce the risk of cutaneous amyloidosis [see Adverse Reactions (6.3)].
- When using VICTOZA with insulin, administer as separate injections. Never mix. It is acceptable to inject VICTOZA and insulin in the same body region but the injections should not be adjacent to each other.
- If a dose is missed, resume the once-daily regimen as prescribed with the next scheduled dose. Do not administer an extra dose or increase the dose to make up for the missed dose.
- If more than 3 days have elapsed since the last VICTOZA dose, reinitiate VICTOZA at 0.6 mg to mitigate any gastrointestinal symptoms associated with reinitiation of treatment. Upon reinitiation, VICTOZA should be titrated at the discretion of the prescriber.

2.2 Adult Dosage

- Initiate VICTOZA with a dose of 0.6 mg daily for one week. The 0.6 mg dose is a starting dose intended to reduce gastrointestinal symptoms during initial titration, and is not effective for glycemic control in adults. After one week at 0.6 mg per day, increase the dose to 1.2 mg daily.

- If additional glycemic control is required, increase the dose to 1.8 mg daily after at least one week of treatment with the 1.2 mg daily dose.

2.3 Pediatric Dosage

- Initiate VICTOZA with a dose of 0.6 mg daily.
- After at least one week at 0.6 mg daily, the dose may be increased to 1.2 mg daily if additional glycemic control is required.
- If additional glycemic control is required, increase the dose to 1.8 mg daily after at least one week of treatment with the 1.2 mg daily dose.

3 DOSAGE FORMS AND STRENGTHS

Injection: 18 mg/3 mL (6 mg/mL) clear, colorless solution in a pre-filled, single-patient-use pen that delivers doses of 0.6 mg, 1.2 mg, or 1.8 mg.

4 CONTRAINDICATIONS

• Medullary Thyroid Carcinoma

VICTOZA is contraindicated in patients with a personal or family history of medullary thyroid carcinoma (MTC) or in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

• Hypersensitivity

VICTOZA is contraindicated in patients with a serious hypersensitivity reaction to liraglutide or to any of the excipients in VICTOZA. Serious hypersensitivity reactions including anaphylactic reactions and angioedema have been reported with VICTOZA [see *Warnings and Precautions* (5.6)].

5 WARNINGS AND PRECAUTIONS

5.1 Risk of Thyroid C-cell Tumors

Liraglutide causes dose-dependent and treatment-duration-dependent thyroid C-cell tumors (adenomas and/or carcinomas) at clinically relevant exposures in both genders of rats and mice [see *Nonclinical Toxicology* (13.1)]. Malignant thyroid C-cell carcinomas were detected in rats and mice. It is unknown whether VICTOZA will cause thyroid C-cell tumors, including medullary thyroid carcinoma (MTC), in humans, as the human relevance of liraglutide-induced rodent thyroid C-cell tumors has not been determined.

Cases of MTC in patients treated with VICTOZA have been reported in the postmarketing period; the data in these reports are insufficient to establish or exclude a causal relationship between MTC and VICTOZA use in humans.

VICTOZA is contraindicated in patients with a personal or family history of MTC or in patients with MEN 2.

Counsel patients regarding the potential risk for MTC with the use of VICTOZA and inform them of symptoms of thyroid tumors (e.g., a mass in the neck, dysphagia, dyspnea, persistent hoarseness).

Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with VICTOZA. Such monitoring may increase the risk of unnecessary procedures, due to low test specificity for serum calcitonin and a high background incidence of thyroid disease. Significantly elevated serum calcitonin may indicate MTC and patients with MTC usually have calcitonin values >50 ng/L. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated. Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.

5.2 Pancreatitis

Based on spontaneous postmarketing reports, acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with VICTOZA. After initiation of VICTOZA,

sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, VICTOZA should promptly be discontinued and appropriate management should be initiated. If pancreatitis is confirmed, VICTOZA should not be restarted.

In glycemic control trials of VICTOZA, there have been 13 cases of pancreatitis among VICTOZA-treated patients and 1 case in a comparator (glimepiride) treated patient (2.7 vs. 0.5 cases per 1000 patient-years). Nine of the 13 cases with VICTOZA were reported as acute pancreatitis and four were reported as chronic pancreatitis. In one case in a VICTOZA-treated patient, pancreatitis, with necrosis, was observed and led to death; however clinical causality could not be established. Some patients had other risk factors for pancreatitis, such as a history of cholelithiasis or alcohol abuse.

VICTOZA has been studied in a limited number of patients with a history of pancreatitis. It is unknown if patients with a history of pancreatitis are at higher risk for development of pancreatitis on VICTOZA.

5.3 Never Share a VICTOZA Pen Between Patients

VICTOZA pens must never be shared between patients, even if the needle is changed. Pen-sharing poses a risk for transmission of blood-borne pathogens.

5.4 Hypoglycemia

Adult patients receiving VICTOZA in combination with an insulin secretagogue (e.g., sulfonylurea) or insulin may have an increased risk of hypoglycemia, including severe hypoglycemia. In pediatric patients 10 years of age and older, the risk of hypoglycemia was higher with VICTOZA regardless of insulin and/or metformin use. [*see Adverse Reactions (6.1), Drug Interactions (7.2)*].

The risk of hypoglycemia may be lowered by a reduction in the dose of sulfonylurea (or other concomitantly administered insulin secretagogues) or insulin. Inform patients using these concomitant medications and pediatric patients of the risk of hypoglycemia and educate them on the signs and symptoms of hypoglycemia.

5.5 Renal Impairment

VICTOZA has not been found to be directly nephrotoxic in animal studies or clinical trials.

There have been postmarketing reports of acute renal failure and worsening of chronic renal failure, which may sometimes require hemodialysis in VICTOZA-treated patients [*see Adverse Reactions (6.2)*]. Some of these events were reported in patients without known underlying renal disease. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration [*see Adverse Reactions (6.1)*]. Some of the reported events occurred in patients receiving one or more medications known to affect renal function or hydration status. Altered renal function has been reversed in many of the reported cases with supportive treatment and discontinuation of potentially causative agents, including VICTOZA. Use caution when initiating or escalating doses of VICTOZA in patients with renal impairment [*see Use in Specific Populations (8.6)*].

5.6 Hypersensitivity Reactions

There have been postmarketing reports of serious hypersensitivity reactions (e.g., anaphylactic reactions and angioedema) in patients treated with VICTOZA. If a hypersensitivity reaction occurs, discontinue VICTOZA; treat promptly per standard of care, and monitor until signs and symptoms resolve. Do not use in patients with a previous hypersensitivity reaction to VICTOZA [*see Contraindications (4)*].

Anaphylaxis and angioedema have been reported with other GLP-1 receptor agonists. Use caution in a patient with a history of anaphylaxis or angioedema with another GLP-receptor agonist because it is unknown whether such patients will be predisposed to these reactions with VICTOZA.

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.