

VICTOZA (liraglutide [rDNA origin] injection)

Highlighted Information for Prescribers

This information is being provided to prescribers of VICTOZA as part of the Risk Evaluation and Mitigation Strategy (REMS) plan for VICTOZA. REMS plans have been required by the U.S. Food and Drug Administration (FDA) since 2008 for certain drugs with serious risks to ensure that the benefits of the drug outweigh the risks of the drug.

The purpose of this information is to inform prescribers of VICTOZA about the following:

- potential risk of medullary thyroid carcinoma (MTC)
- risk of acute pancreatitis

INDICATIONS AND USAGE

VICTOZA is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

APPROPRIATE PATIENT SELECTION

- 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 (MEN 2).
- VICTOZA is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise.
- 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 should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
- VICTOZA has not been studied in combination with insulin.

POTENTIAL RISK OF MEDULLARY THYROID CARCINOMA

There is a Boxed Warning for VICTOZA:

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 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 (MEN2). Based on the finding 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.

- Patients with thyroid nodules noted on physical examination or neck imaging obtained for other reasons should be referred to an endocrinologist for further evaluation.
- Although routine monitoring of serum calcitonin is of uncertain value in patients treated with Victoza, if serum calcitonin is measured and found to be elevated, the patient should be referred to an endocrinologist for further evaluation.

RISK OF ACUTE PANCREATITIS

VICTOZA labeling contains a warning describing the risk of acute pancreatitis:

- There are no conclusive data establishing a risk of pancreatitis with VICTOZA treatment.
- After initiation of VICTOZA, and after dose increases, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back, and which may or may not be accompanied by vomiting).
- If pancreatitis is suspected, VICTOZA and other potentially suspect drugs should be discontinued promptly, confirmatory tests should be performed and appropriate management should be initiated.
- If pancreatitis is confirmed, VICTOZA should not be restarted.
- Use with caution in patients with a history of pancreatitis.

Refer to the Full Prescribing Information for further product information.

If you have any questions about these materials, please call the Novo Nordisk Customer Care Center at 1-877-484-2869.

This brochure has been reviewed and approved by the FDA as part of the Victoza REMS.