



VICTOZA[®] REMS (Risk Evaluation and Mitigation Strategy)

FDA Required REMS* Safety Information

- Potential Risk of Medullary Thyroid Carcinoma
- Risk of Acute Pancreatitis

Potential Risk of Medullary Thyroid Carcinoma

BOXED 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.
 - VICTOZA[®] is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN2).
- 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.
 - **Counsel patients** regarding the potential risk of MTC with the use of Victoza and inform them of the symptoms of thyroid tumors (e.g., **mass in the neck, dysphagia, dyspnea or persistent hoarseness**). 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

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

- In clinical trials studying VICTOZA[®], there were more cases of pancreatitis in patients treated with VICTOZA[®] than in patients treated with comparators.
- 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).**
- Discontinue VICTOZA[®] promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed.
- Consider other antidiabetic therapies in patients with a history of pancreatitis.
- VICTOZA[®] has not been studied in patients with a history of pancreatitis.

Indication: VICTOZA[®] (liraglutide) injection is an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

VICTOZA is not recommended as a first-line therapy for patients inadequately controlled on diet and exercise.

* What is the VICTOZA REMS?

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the FDA to manage known or potential serious risks associated with a drug product. FDA has determined that a REMS is necessary to ensure that the benefits of VICTOZA[®] outweigh the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis. Novo Nordisk, Inc. has established an informational program for healthcare professionals to help minimize these risks. This factsheet is required by the FDA as part of the VICTOZA REMS program.

Please visit www.Victoza.com/REMS for further information.

Reporting Adverse Events:

To report adverse events contact:

- Novo Nordisk at 1-877-VICTOZA (1-877-484-2869) and/or
- FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

This factsheet does not contain the complete safety profile for Victoza. Please refer to the Prescribing Information, including Boxed Warning, for further information. If you have any questions about these materials, please call the Novo Nordisk Customer Care Center at 1-877-484-2869.