



VICTOZA[®] REMS

FDA Required REMS Safety Information

- **Potential risk of medullary thyroid carcinoma**
- **Risk of acute pancreatitis associated with VICTOZA[®]**

Important Safety Notice

The FDA has required this notice as part of the VICTOZA[®] REMS (Risk Evaluation and Mitigation Strategy) to inform healthcare providers about the following serious risks:

Potential Risk of Medullary Thyroid Carcinoma

- 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.
- 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.

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.

Because of these risks, VICTOZA is not recommended as a first-line therapy for patients inadequately controlled on diet and exercise.

A non-promotional factsheet, reviewed by the FDA, with more detailed safety information about these risks is enclosed. Please visit www.Victoza.com/REMS for more information about the VICTOZA[®] REMS program.

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

This letter does not contain the complete safety profile for VICTOZA[®]. Please see the Prescribing Information, including Boxed Warning, and Medication Guide, which are enclosed with this letter.

Reporting Adverse Events

You are encouraged to report negative side effects of prescription drugs to the FDA. Please contact Novo Nordisk at 1-877-4-VICTOZA (1-877-484-2869) or contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Sincerely,

Alan C. Moses, M.D.

Global Chief Medical Officer, Novo Nordisk

Enclosure: VICTOZA[®] REMS: FDA Required Safety Information

VICTOZA[®] Full Prescribing Information VICTOZA[®] Medication Guide