

## **IMPORTANT DRUG WARNING CONCERNING VICTOZA®**

### **SUBJECT: POTENTIAL RISKS OF THYROID C-CELL TUMORS AND ACUTE PANCREATITIS ASSOCIATED WITH VICTOZA®**

Dear Healthcare Professional:

This letter is to remind you of important safety information about VICTOZA® (liraglutide [rDNA origin]) injection. VICTOZA® is indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

The Food and Drug Administration (FDA) has required Novo Nordisk to communicate the following risk information to potential prescribers.

You should note the following potential serious risks of VICTOZA®:

- There is potential risk of thyroid C-cell tumors, including medullary thyroid carcinoma (MTC) associated with VICTOZA®
- VICTOZA® may increase the risk of acute pancreatitis

Because of these risks, VICTOZA® is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise.

Additional information about these risks is provided in the remainder of this letter.

#### **Potential Risk of Thyroid C-Cell Tumors, including 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 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).
- 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**

- 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).
- 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.

### **Medullary Thyroid Cancer Registry**

To further assess risk, Novo Nordisk will be systematically monitoring cases of medullary thyroid cancer (MTC) via MTC case series registry to identify any increase in the incidence of MTC related to the introduction of VICTOZA® into the US marketplace. All cases of medullary thyroid cancer, regardless of potential association with any drug treatment, should be reported to your state cancer registry.

To find out information on how to report a case to your state cancer registry, go to <http://www.naaccr.org/Membership/MembershipDirectory.aspx>.

### **Adverse Events**

Healthcare professionals should report any serious adverse events thought to be associated with VICTOZA® use to:

- Novo Nordisk at 1-877-4-VICTOZA (1-877-484-2869)
- FDA's MedWatch reporting system:
  - by phone at 1-800-FDA-1088 (1-800-332-1088)
  - by facsimile at 1-800-FDA-0178 (1-800-332-0178)
  - by mail using FDA Form 3500
  - online (<http://www.fda.gov/medwatch/index.html>)

Sincerely,



Alan C. Moses, M.D.

Global Chief Medical Officer, Novo Nordisk  
Enclosure: VICTOZA® Full Prescribing Information