A REMS (Risk Evaluation and Mitigation Strategy) is a strategy required by the Food and Drug Administration (FDA) to manage known or potential serious risks associated with a drug product to ensure the benefits of a drug outweigh its risks.

The purpose of the VICTOZA® REMS is 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
Potential Risk of Thyroid C-Cell Tumors

**Appropriate Patient Selection**

- VICTOZA® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN2)
- VICTOZA® is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise

**Patient Management**

- 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 and to rule out thyroid C-cell tumor
Risk of Pancreatitis

**Appropriate Patient Selection**

- VICTOZA® has not been studied sufficiently in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

**Patient Management**

- 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 promptly if pancreatitis is suspected.
- Do not restart if pancreatitis is confirmed.
- Consider other antidiabetic therapies in patients with a history of pancreatitis.