Trulicity™ REMS (Risk Evaluation and Mitigation Strategy)

What is the Trulicity REMS?

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

The purpose of the Trulicity REMS is to inform healthcare providers (HCPs) about the following risks of Trulicity:

- Potential Risk of Medullary Thyroid Carcinoma (MTC)
  - In male and female rats, dulglicline causes a dose-related and treatment-duration-dependent increase in the incidence of thyroid C-cell tumors after lifetime exposure.
  - It is unknown whether Trulicity causes thyroid C-cell tumors, including MTC, in humans as human relevance of dulaglutide-induced rodent thyroid C-cell tumors has not been determined.
  - Cases of MTC in patients treated with tiraglutide, another GLP-1 receptor agonist, have been reported in the postmarketing period. The data in these reports are insufficient to establish or exclude a causal relationship between MTC and GLP-1 receptor agonist use in humans.
  - Counsel patients regarding the risk of MTC and the symptoms of thyroid tumors.

- Risk of Pancreatitis
  - Pancreatitis has been reported with the use of GLP-1 receptor agonists. Cases of pancreatitis have been described in association with Trulicity during clinical trials.
  - Discontinue promptly if pancreatitis is suspected. Do not restart if pancreatitis is confirmed. Consider other anti-diabetic therapies in patients with a history of pancreatitis.

A non-promotional fact sheet, reviewed by FDA, with more detailed safety information about these risks is available.