SAXENDA® REMS: Risk Evaluation and Mitigation Strategy

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 SAXENDA REMS is to inform healthcare providers of the following serious risks associated with SAXENDA:

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

Please see Important Safety Information in this presentation.
Please see Prescribing Information.
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 SAXENDA® 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.
### Potential Risk of Medullary Thyroid Carcinoma (2)

**Appropriate Patient Selection**
- **SAXENDA®** is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN2).

**Patient Management**
- **Counsel patients** regarding the risk for MTC and inform them of symptoms of thyroid tumors (e.g., **mass in the neck**, **dysphagia**, **dyspnea**, **persistent hoarseness**).

  - **Instruct patients** to contact their healthcare provider promptly if these symptoms occur.

  - Patients with thyroid nodules noted on physical examination or neck imaging should be further evaluated.
Potential Risk of Medullary Thyroid Carcinoma (3)

**Patient Management**

- Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value in patients treated with SAXENDA®. If serum calcitonin is measured and found to be elevated, the patient should be further evaluated.
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 liraglutide.

- In clinical trials studying SAXENDA®, there were more cases of pancreatitis in patients treated with SAXENDA® than in patients treated with placebo.
Risk of Acute Pancreatitis (2)

Appropriate Patient Selection

- SAXENDA® has not been studied sufficiently in patients with a history of pancreatitis.

Patient Management

- After initiation of SAXENDA®, and after dose increases, observe patients carefully for signs and symptoms of pancreatitis.

- Counsel patients to contact their healthcare provider promptly if they experience 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.

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