FDA Required REMS* Safety Information

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

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.
- SAXENDA® is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN2).
- 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). Patients with thyroid nodules noted on physical examination or neck imaging should also be further evaluated.
- Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC 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.
- SAXENDA® has not been studied sufficiently in patients with a history of pancreatitis.
- 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 (e.g., 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.

**Indication:** SAXENDA® is indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of:
  - 30 kg/m² or greater (obese), or
  - 27 kg/m² or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia).

*What is the SAXENDA® REMS?*

A REMS (Risk Evaluation and Mitigation Strategy) is a program required by the FDA to manage known or potential serious risks associated with a drug product. FDA has determined that a REMS is necessary to ensure that the benefits of SAXENDA® outweigh the potential risk of medullary thyroid carcinoma and the risk of acute pancreatitis. This factsheet is required by the FDA as part of the SAXENDA® REMS program.

Please visit [www.SAXENDA.com/REMS](http://www.SAXENDA.com/REMS) for further information.

**Reporting Adverse Events:**

To report adverse events, contact:
- Novo Nordisk at 1-844-363-4448 and/or
- FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

*This factsheet does not contain the complete safety profile for SAXENDA®. Please refer to the Prescribing Information, including Boxed Warning, for further information.*

If you have any questions about these materials, please call the Novo Nordisk Customer Care Center at 1-844-363-4448.