

## SAXENDA<sup>®</sup> REMS (Risk Evaluation and Mitigation Strategy)

### 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>. 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<sup>®</sup>, there were more cases of pancreatitis in patients treated with SAXENDA<sup>®</sup> than in patients treated with placebo.
- SAXENDA<sup>®</sup> has not been studied sufficiently in patients with a history of pancreatitis.
- After initiation of SAXENDA<sup>®</sup>, 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<sup>®</sup> 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/m<sup>2</sup> or greater (obese), or
- 27 kg/m<sup>2</sup> or greater (overweight) in the presence of at least one weight-related comorbid conditions (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia).

### \* What is the SAXENDA<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>. 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.