Saxenda®
liraglutide (rDNA origin) injection

SAXENDA® 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® 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/m^2 or greater (obese), or
- 27 kg/m^2 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® 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 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.

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.