SAXENDA® REMS

FDA Required REMS Safety Information

- **Potential risk of medullary thyroid carcinoma**
- **Risk of acute pancreatitis**

Important Safety Notice

The FDA has required this notice as part of the SAXENDA® REMS (Risk Evaluation and Mitigation Strategy) to inform healthcare providers about the following **serious risks of SAXENDA® (liraglutide)**:

Potential Risk of Medullary Thyroid Carcinoma

- 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.

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.

A non-promotional factsheet, reviewed by the FDA, with more detailed safety information about these risks is enclosed. Please visit www.SAXENDA.com/REMS for more information about the SAXENDA® REMS program.

Indication: SAXENDA® (liraglutide) injection 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:

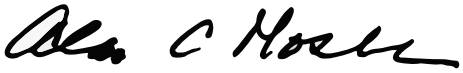
- 30 kg/m^2 or greater (obese), or
- 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus or dyslipidemia).

This letter does not contain the complete safety profile for SAXENDA®. Please see the Prescribing Information, including Boxed Warning, and Medication Guide, which are enclosed with this letter.

Reporting Adverse Events

You are encouraged to report negative side effects of prescription drugs to the FDA. Please contact Novo Nordisk at 1-844-363-4448 or contact the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Sincerely,



Alan C. Moses, M.D.
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Enclosure: SAXENDA® REMS: FDA Required Safety Information
SAXENDA® Full Prescribing Information SAXENDA® Medication Guide