**SAXENDA® REMS PROGRAM**

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 about the following serious risks:

**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.

Please see the non-promotional SAXENDA® REMS Factsheet for Prescribers, reviewed by the FDA, for further information on these risks.
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JAMES P SMITH
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