XULTOPHY® 100/3.6 REMS: Risk Evaluation and Mitigation Strategy

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 XULTOPHY® 100/3.6 REMS is to inform healthcare providers of the following serious risks associated with XULTOPHY® 100/3.6:

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

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Xultophy® 100/3.6
(insulin degludec and liraglutide injection)

Potential Risk of Medullary Thyroid Carcinoma

BOXED WARNING: RISK OF THYROID C-CELL TUMORS

- Liraglutide, one of the components of XULTOPHY® 100/3.6, 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 XULTOPHY® 100/3.6 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.

Potential Risk of Medullary Thyroid Carcinoma (2)

- Cases of MTC in patients treated with liraglutide have been reported in the postmarketing period; the data in these reports are insufficient to establish or exclude a causal relationship between MTC and liraglutide use in humans.

Potential Risk of Medullary Thyroid Carcinoma (3)

Appropriate Patient Selection

- XULTOPHY® 100/3.6 is contraindicated in patients with a personal or family history of MTC and in patients with Multiple Endocrine Neoplasia syndrome type 2 (MEN2).
- XULTOPHY® 100/3.6 is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise.

Potential Risk of Medullary Thyroid Carcinoma (4)

Patient Management

- **Counsel patients** regarding the risk for MTC and inform them of symptoms of thyroid tumors (e.g., **mass in the neck, dysphagia, persistent hoarseness**).
- **Instruct patients** to contact their healthcare provider promptly if these symptoms occur.
- Patients with thyroid nodules noted on physical examination or neck imaging should be further evaluated.
- Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value in patients treated with XULTOPHY® 100/3.6.
- If serum calcitonin is measured and found to be elevated, the patient should be further evaluated.

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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.

Risk of Acute Pancreatitis (2)

Appropriate Patient Selection

- XULTOPHY® 100/3.6 has not been studied sufficiently in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.

Patient Management

- After initiation of XULTOPHY® 100/3.6, 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 (including **persistent severe abdominal pain, sometimes radiating to the back, and which may or may not be accompanied by vomiting**).
- Discontinue XULTOPHY® 100/3.6 if pancreatitis is suspected.
- Do not restart if pancreatitis is confirmed.

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