

# Xultophy® 100/3.6

(insulin degludec and liraglutide injection)

## XULTOPHY® 100/3.6 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 XULTOPHY® 100/3.6 REMS (Risk Evaluation and Mitigation Strategy) to inform healthcare providers about the following **serious risks of Xultophy® 100/3.6 (insulin degludec/liraglutide)**:

#### **Potential Risk of Medullary Thyroid Carcinoma**

- **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.
- 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.

#### **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.**

Because of these risks, XULTOPHY® 100/3.6 is not recommended as a first-line therapy for patients inadequately controlled on diet and exercise.

A non-promotional factsheet, reviewed by the FDA, with more detailed safety information about these risks is enclosed. Please visit [www.xultophy10036pro.com/REMS](http://www.xultophy10036pro.com/REMS) for more information about the XULTOPHY® 100/3.6 REMS program.

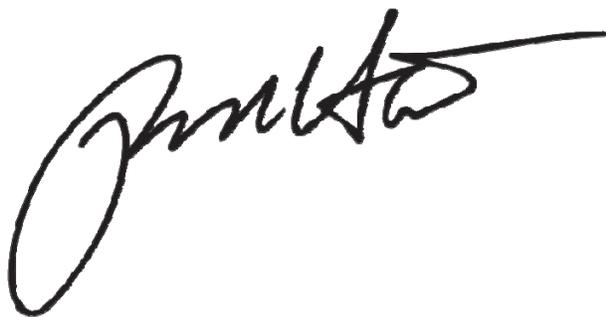
**Indication:** XULTOPHY® 100/3.6 is a combination of insulin degludec and liraglutide, indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 50 units daily) or liraglutide (less than or equal to 1.8 mg daily).

This letter does not contain the complete safety profile for XULTOPHY® 100/3.6. 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 1-800-727-6500 or contact the FDA at 1-800-FDA-1088 or [www.fda.gov/medwatch](http://www.fda.gov/medwatch).

Sincerely,

A handwritten signature in black ink, appearing to read 'Todd Hobbs', with a long horizontal flourish extending to the right.

Todd Hobbs, M.D.

Vice President, North America, Chief Medical Officer, Novo Nordisk

Enclosure: XULTOPHY® 100/3.6 REMS: FDA Required Safety Information

XULTOPHY® 100/3.6 Full Prescribing Information

XULTOPHY® 100/3.6 Medication Guide

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