

Xultophy® 100/3.6 ONCE DAILY

ONE STARTING DOSE FOR ALL PATIENTS¹

START

Convert from basal insulin or liraglutide¹

16 UNITS

16 units=16 units of insulin degludec and 0.58 mg liraglutide

- Therapy with basal insulin and liraglutide should be discontinued prior to initiation of Xultophy® 100/3.6
- No waiting to inject when removed from the refrigerator

TITRATE

Every 3 to 4 days based on FPG¹

Below FPG target

-2
units

Within FPG target
(72-90 mg/dL)³

0
units

Above FPG target

+2
units

- Maximum dose: 50 units=50 units of insulin degludec and 1.8 mg liraglutide
- In clinical trials, patients adjusted their doses on Monday and Thursday of each week²

Xultophy® 100/3.6 is dosed once daily at the same time each day with or without food



Delivers a fixed-ratio combination in increments of 1 unit
1 unit=1 unit of insulin degludec and 0.036 mg liraglutide

FPG=fasting plasma glucose.

³Xultophy® 100/3.6 (Studies A, B, and C) and basal insulin comparators (Studies B and C) were titrated to target twice weekly by increments or decrements of 2 units of Xultophy® 100/3.6 or 2 units basal insulin, respectively, toward a prespecified FPG target of 72 to 90 mg/dL. In Study B, titration in the comparator arm was limited by a maximum dose of 50 units of insulin degludec.

Indications and Limitations of Use

Xultophy® 100/3.6 (insulin degludec and liraglutide injection) 100 units/mL and 3.6 mg/mL is a combination of insulin degludec and liraglutide and is 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).

- Xultophy® 100/3.6 is not recommended as first-line therapy for patients who have inadequate glycemic control on diet and exercise.
- Xultophy® 100/3.6 has not been studied in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Xultophy® 100/3.6 is not recommended for use in combination with any other product containing liraglutide or another GLP-1 receptor agonist.
- Xultophy® 100/3.6 is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
- Xultophy® 100/3.6 has not been studied in combination with prandial insulin.

Important Safety Information

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.
- 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 (MEN 2). Counsel patients regarding the potential risk for MTC with the use of Xultophy® 100/3.6 and inform them of symptoms of thyroid tumors (e.g. a mass in the neck, dysphagia, dyspnea, persistent hoarseness). Routine monitoring of serum calcitonin or using thyroid ultrasound is of uncertain value for early detection of MTC in patients treated with Xultophy® 100/3.6.



Please see additional Important Safety Information on the next page.
Please [click here](#) for Prescribing Information.

Xultophy® 100/3.6
insulin degludec 100 units/mL and
liraglutide 3.6 mg/mL injection

How to prescribe Xultophy® 100/3.6¹

Adding to your e-prescribing system

DRUG NAME:	Xultophy® 100/3.6
FORM/STRENGTH:	100 units/mL insulin degludec and 3.6 mg/mL liraglutide
QUANTITY:	15 mL (5 pens, 3 mL each) 1500 units total
DOSAGE FORM:	Solution
NDC:	0169-2911-15

Rx

Xultophy 100/3.6
Sig: 16 units once daily
Titrate as directed
5-pen box, 3 mL each
Refill: 2

- Provide a second prescription for NovoFine® Plus 32G pen needles
- Provide titration instructions with FPG target range

Learn more at Xultophy10036Pro.com

Important Safety Information (cont'd)

CONTRAINDICATIONS

- Xultophy® 100/3.6 is contraindicated during episodes of hypoglycemia and in patients with hypersensitivity to Xultophy® 100/3.6, either of the active substances, or any of its excipients.

WARNINGS AND PRECAUTIONS

- **Risk of Thyroid C-cell Tumors:** If serum calcitonin is measured and found to be elevated or thyroid nodules are noted on physical examination or neck imaging, the patient should be further evaluated.
- **Pancreatitis:** Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with liraglutide postmarketing. Observe patients carefully for signs and symptoms of pancreatitis (persistent severe abdominal pain, sometimes radiating to the back with or without vomiting). If pancreatitis is suspected, discontinue Xultophy® 100/3.6 promptly and if pancreatitis is confirmed, do not restart. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- **Never Share a Xultophy® 100/3.6 Pen Between Patients,** even if the needle is changed. Sharing of the pen poses a risk for transmission of blood-borne pathogens.
- **Hyper- or Hypoglycemia with Changes in Xultophy® 100/3.6 Regimen:** Monitor blood glucose in all patients. Changes in Xultophy® 100/3.6 regimen may affect glycemic control. Changes should be made cautiously and under medical supervision. Adjustments in concomitant oral anti-diabetic treatment may be needed.
- **Overdose Due to Medication Errors:** Instruct patients to check the label before each injection since accidental mix-ups with insulin containing products can occur. Do not administer more than 50 units of Xultophy® 100/3.6 daily. Do not exceed the 1.8 mg maximum recommended dose of liraglutide or use with other GLP-1 receptor agonists.
- **Hypoglycemia:** Hypoglycemia is the most common adverse reaction of insulin containing products, including Xultophy® 100/3.6, and may be life-threatening. Increase monitoring with changes to: dose, co-administered glucose lowering medications, meal pattern, physical activity; and in patients with hypoglycemia unawareness or renal or hepatic impairment.
- **Acute Kidney Injury:** Acute renal failure and worsening of chronic renal failure, which may sometimes require hemodialysis, have been reported postmarketing for liraglutide, usually in association with nausea, vomiting, diarrhea, or dehydration. Advise patients of the potential risk of dehydration due to gastrointestinal adverse reactions and take precautions to avoid fluid depletion.

- **Hypersensitivity and Allergic Reactions:** Severe, life-threatening, generalized allergy, including anaphylaxis, angioedema, bronchospasm, hypotension, and shock can occur. If a hypersensitivity reaction occurs, discontinue and treat per standard of care.
- **Hypokalemia:** All insulin containing products, including Xultophy® 100/3.6 can lead to life-threatening hypokalemia, which may then cause respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk for hypokalemia and treat if indicated.
- **Fluid Retention and Congestive Heart Failure:** Patients using insulin containing products, including Xultophy® 100/3.6, with thiazolidinediones (TZDs), which are PPAR-gamma agonists, should be observed for signs and symptoms of heart failure. If heart failure develops, dosage reduction or discontinuation of the TZD must be considered.
- **Macrovascular Outcomes:** There have been no studies establishing conclusive evidence of macrovascular risk reduction with Xultophy® 100/3.6.

ADVERSE REACTIONS

- The most common adverse reactions, reported in ≥5% of patients treated with Xultophy® 100/3.6 are nasopharyngitis, headache, nausea, diarrhea, increased lipase and upper respiratory tract infection.

DRUG INTERACTIONS

- Certain drugs may affect glucose metabolism, requiring dose adjustment and close monitoring of blood glucose. The signs and symptoms of hypoglycemia may be reduced or absent in patients taking anti-adrenergic drugs (e.g., beta-blockers, clonidine, guanethidine, and reserpine).
- Liraglutide-containing products, including Xultophy® 100/3.6, cause a delay of gastric emptying, and thereby have the potential to impact the absorption of concomitantly administered oral medications. Caution should be exercised when oral medications are concomitantly administered with liraglutide-containing products.

USE IN SPECIFIC POPULATIONS

- Xultophy® 100/3.6 should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

References: 1. Xultophy 100/3.6 [package insert]. Plainsboro, NJ: Novo Nordisk Inc; November 2016. 2. Lingvay I, Pérez Manghi F, García-Hernández P, et al; DUAL V Investigators. Effect of insulin glargine up-titration vs insulin degludec/liraglutide on glycated hemoglobin levels in patients with uncontrolled type 2 diabetes: the DUAL V randomized clinical trial. *JAMA*. 2016;315(9):898-907.

Please see additional Important Safety Information, including Boxed Warning, on previous page. Please [click here](#) for Prescribing Information.



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insulin degludec 100 units/mL and
liraglutide 3.6 mg/mL injection