

## Ask your health care provider about Xultophy® 100/3.6



Could Xultophy® 100/3.6 be the next step in your diabetes treatment? **Get the most out of your next appointment.** Print this guide, then use it during a conversation with your health care provider.



### Questions to ask your health care provider

- What is my current A1C number, and what is my goal?
- Is my current medicine doing enough to get me to my goals?
- Could Xultophy® 100/3.6 replace my current medicine?
- Do I need to take Xultophy® 100/3.6 with meals?
- What are some possible side effects of Xultophy® 100/3.6?
- Do I have commercial insurance coverage for Xultophy® 100/3.6?

**Additional questions I have:**

### Selected Important Safety Information

#### What is the most important information I should know about Xultophy® 100/3.6?

##### Xultophy® 100/3.6 may cause serious side effects, including:

- **Possible thyroid tumors, including cancer.** Tell your health care provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer. In studies with rats and mice, liraglutide, one of the components of Xultophy® 100/3.6, and medicines that work like liraglutide caused thyroid tumors, including thyroid cancer. It is not known if Xultophy® 100/3.6 will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people.

##### Who should not use Xultophy® 100/3.6? Do not use Xultophy® 100/3.6 if:

- you or any of your family have ever had MTC or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- you are having an episode of low blood sugar.
- you are allergic to insulin degludec, liraglutide, or any of the ingredients in Xultophy® 100/3.6.

Please see additional Important Safety Information on the following page.

Please [click here](http://www.novo-pi.com/xultophy10036.pdf) for Prescribing Information and Medication Guide or visit <http://www.novo-pi.com/xultophy10036.pdf>.

## Indication and Usage

### What is Xultophy® 100/3.6 (insulin degludec and liraglutide injection) 100 units/mL and 3.6 mg/mL?

Xultophy® 100/3.6 is an injectable prescription medicine that contains 2 diabetes medicines, insulin degludec, 100 units/mL, and liraglutide, 3.6 mg/mL. Xultophy® 100/3.6 should be used along with diet and exercise to lower blood sugar (glucose) in adults with type 2 diabetes mellitus.

- Xultophy® 100/3.6 is not recommended as the first choice of medicine for treating diabetes.
- Xultophy® 100/3.6 is not recommended for use in combination with any other product containing liraglutide or another glucagon like peptide 1 receptor agonist (GLP-1 RA).
- Xultophy® 100/3.6 is not for use in people with type 1 diabetes or people with diabetic ketoacidosis (increased ketones in the blood or urine).
- It is not known if Xultophy® 100/3.6 can be used with mealtime insulin.
- It is not known if Xultophy® 100/3.6 is safe and effective for use in children.

## Important Safety Information

### What is the most important information I should know about Xultophy® 100/3.6?

#### Xultophy® 100/3.6 may cause serious side effects, including:

- **Possible thyroid tumors, including cancer.** Tell your health care provider if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer. In studies with rats and mice, liraglutide, one of the components of Xultophy® 100/3.6, and medicines that work like liraglutide caused thyroid tumors, including thyroid cancer. It is not known if Xultophy® 100/3.6 will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people.

### Who should not use Xultophy® 100/3.6?

#### Do not use Xultophy® 100/3.6 if:

- you or any of your family have ever had MTC or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- you are having an episode of low blood sugar or if you are allergic to insulin degludec, liraglutide, or any of the ingredients in Xultophy® 100/3.6.

### What should I tell my health care provider before using Xultophy® 100/3.6?

#### Tell your health care provider about all your medical conditions, including if you:

- have or have had problems with your pancreas, kidneys, or liver.
- have heart failure or other heart problems. If you have heart failure, it may get worse while you take TZDs (thiazolidinediones) with Xultophy® 100/3.6.
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food.
- are taking certain medicines called GLP-1 RA, or have had an allergic reaction to a GLP-1 RA.
- are pregnant or breastfeeding or plan to become pregnant or breastfeed. It is not known if Xultophy® 100/3.6 passes into your breast milk.

Tell your health care provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. **Before using Xultophy® 100/3.6, talk to your health care provider about low blood sugar and how to manage it.**

Please see additional Important Safety Information on the following page.

Please [click here](#) for Prescribing Information and Medication Guide or visit <http://www.novo-pi.com/xultophy10036.pdf>.

## Important Safety Information (cont'd)

### How should I use Xultophy® 100/3.6?

- Read the **Instructions for Use** and take Xultophy® 100/3.6 exactly as your health care provider tells you.
- Do not change your dosing schedule without first talking to your health care provider.
- **Do not** inject Xultophy® 100/3.6 into a muscle or vein or use in an insulin infusion pump.
- **Use Xultophy® 100/3.6 at the same time each day with or without food. Do not take more than 50 units of Xultophy® 100/3.6 each day.**
- Check the Pen label each time you give your injection to make sure you are using the correct medicine.
- **Change (rotate) your injection sites within the area you choose with each injection** to reduce your risk of getting lipodystrophy (pits in skin or thickened skin) and localized cutaneous amyloidosis (skin with lumps) at the injection sites.
  - **Do not** use the exact same spot for each injection.
  - **Do not** inject where the skin has pits, is thickened, or has lumps.
  - **Do not** inject where the skin is tender, bruised, scaly or hard, or into scars or damaged skin.
- **Do not share your Xultophy® 100/3.6 pen with other people, even if the needle has been changed.** You may give other people a serious infection, or get a serious infection from them.
- **Check your blood sugar levels.** Ask your health care provider what your blood sugar levels should be and when you should check them.

Your dose of Xultophy® 100/3.6 may need to change because of change in level of physical activity or exercise, weight gain or loss, increased stress, illness, change in diet, or other medicines you take.

### What should I avoid while taking Xultophy® 100/3.6?

- **Do not** drive or operate heavy machinery, until you know how Xultophy® 100/3.6 affects you. **Do not** drink alcohol or use prescription or over-the-counter medicines that contain alcohol.

### What are the possible side effects of Xultophy® 100/3.6?

#### Xultophy® 100/3.6 may cause serious side effects that can be life-threatening, including:

- **inflammation of your pancreas (pancreatitis).** Stop using Xultophy® 100/3.6 and call your health care provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your abdomen to your back.
- **low blood sugar (hypoglycemia).** Your risk for getting low blood sugar may be higher if you use Xultophy® 100/3.6 with another medication that can cause low blood sugar. Signs and symptoms of low blood sugar may include: shakiness, irritability, fast heartbeat, dizziness, weakness, sweating, confusion, drowsiness, hunger, headache, and feeling jittery.
- **kidney problems (kidney failure).** Worsening of kidney failure and sudden kidney failure have happened in people with kidney problems and in people without kidney problems, who have taken liraglutide, one of the ingredients in Xultophy® 100/3.6. Diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems to get worse. Tell your health care provider if you have diarrhea, nausea, or vomiting. Drink plenty of fluids to help reduce your risk of dehydration during treatment with Xultophy® 100/3.6.
- **serious allergic reactions.** Stop using Xultophy® 100/3.6 and get medical help right away if you have any symptoms of a serious allergic reaction, including swelling of your face, lips, tongue or throat, problems breathing or swallowing, severe rash or itching, fainting or feeling dizzy, or a fast heartbeat.
- **gallbladder problems.** Gallbladder problems have happened in some people who take liraglutide, an ingredient in Xultophy® 100/3.6. Tell your health care provider right away if you get symptoms of gallbladder problems including pain in the right or middle upper stomach area, fever, nausea and vomiting, or your skin or the white part of your eyes turn yellow.
- **low potassium in your blood (hypokalemia).**
- **heart failure.** Taking certain diabetes medicines called TZDs with Xultophy® 100/3.6 may cause heart failure in some people. This can happen even if you have never had heart failure or heart problems. If you already have heart failure, it may get worse while you take TZDs with Xultophy® 100/3.6. Tell your health care provider if you have any new or worse symptoms of heart failure, including shortness of breath, tiredness, swelling of your ankles or feet, and sudden weight gain.

The most common side effects of Xultophy® 100/3.6 may include stuffy or runny nose, sore throat, headache, nausea, diarrhea, increased blood levels of lipase, and upper respiratory tract infection.

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Xultophy® 100/3.6 is a prescription medication.

Talk to your health care provider about the importance of diet and exercise in your treatment plan.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit [www.FDA.gov/medwatch](http://www.FDA.gov/medwatch), or call 1-800-FDA-1088.



If you need assistance with prescription drug costs, help may be available.  
Visit [pparx.org](http://pparx.org) or call 1-888-4PPA-NOW.



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