

## READ THIS FOR SAFE AND EFFECTIVE USE OF YOUR MEDICINE

### PATIENT MEDICATION INFORMATION

**PrXULTOPHY<sup>®</sup>**  
**insulin degludec+liraglutide injection**  
**(Zul-to-fye)**

Read this carefully before you start taking Xultophy<sup>®</sup> and each time you get a refill. This leaflet is a summary and will not tell you everything about this drug. Talk to your healthcare professional about your medical condition and treatment and ask if there is any new information about Xultophy<sup>®</sup>.

Keep this leaflet. You may need to read it again. If you have any further questions, ask your doctor, pharmacist or nurse. This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See '*What are the Possible Side Effects From Using Xultophy<sup>®</sup>*'.

#### **Serious Warnings and Precautions**

- Low blood sugar is the most common adverse effect of insulin, including Xultophy<sup>®</sup>.
- If low blood sugar or high blood sugar reactions are not treated they can result in the loss of consciousness, coma or death.
- Blood sugar levels should be monitored for all patients with diabetes.
- Any change of insulin should be made cautiously and only under medical supervision. This may result in dosage adjustment.
- Never inject your insulin directly into a vein.
- Never use Xultophy<sup>®</sup> in insulin infusion pumps.
- Only use Xultophy<sup>®</sup> if it appears water clear or colourless.
- Xultophy<sup>®</sup> must not be mixed with any other insulin.
- Possible Risk of thyroid tumours, including cancer
- As part of drug testing, liraglutide, one of the ingredients in Xultophy<sup>®</sup> was given to rats and mice in long term studies. In these studies, liraglutide caused both rats and mice to develop medullary thyroid tumours, some of which were cancer. It is not known if liraglutide will cause thyroid tumours or a type of thyroid cancer called medullary thyroid cancer in people. Medullary thyroid cancer in humans is rare; however it is serious and potentially fatal.
- If you develop tumours of the thyroid, it may have to be surgically removed. You should discuss any safety concerns you have about the use of liraglutide with your doctor.

#### **What is Xultophy<sup>®</sup> used for?**

Xultophy<sup>®</sup> is used in combination with metformin, with or without sulfonylurea, to improve blood glucose (sugar) levels in adult patients with type 2 diabetes mellitus. You have diabetes because your body:

- Does not make enough insulin to control the level of sugar in your blood, or
- Is not able to use the insulin properly.

Xultophy<sup>®</sup> should not be used in type 1 diabetes (formerly known as insulin-dependent diabetes mellitus or IDDM) or for the treatment of diabetic ketoacidosis (increased ketones in the blood or urine).

### **How does Xultophy<sup>®</sup> work?**

Xultophy<sup>®</sup> contains two active substances that help your body control your blood sugar:

- Insulin degludec – a long-acting basal insulin which lowers your blood sugar levels, and
- Liraglutide – a ‘GLP-1 receptor agonist’ that helps your body make more insulin during meals and lowers the amount of sugar made by your body.

### If you use GLP-1 treatment

You should stop your GLP-1 treatment prior to starting on Xultophy<sup>®</sup>.

### If you use basal insulin

You should stop your basal insulin treatment prior to starting on Xultophy<sup>®</sup>.

### **What are the ingredients in Xultophy<sup>®</sup>?**

Medicinal ingredients: The active substances are insulin degludec and liraglutide. Each mL of solution contains 100 units of insulin degludec and 3.6 mg liraglutide. Each unused pre-filled pen (3 mL) contains 300 units of insulin degludec and 10.8 mg liraglutide.

Non-medicinal ingredients: glycerol, phenol, zinc acetate, hydrochloric acid and sodium hydroxide (for pH adjustment), and water for injections.

### **Xultophy<sup>®</sup> comes in the following dosage forms:**

Xultophy<sup>®</sup> is an injection supplied as a sterile, clear, colorless solution in a 3 mL pre-filled, disposable, single-patient use pen injector.

The pre-filled pen can provide from 1 up to 50 units in one injection in increments of one unit.

The pre-filled pen is recommended to be used with NovoFine<sup>®</sup> or NovoTwist<sup>®</sup> injection needles up to a length of 8 mm and as thin as 32G.

### **Do not use Xultophy<sup>®</sup> if:**

- You are allergic to insulin degludec or liraglutide or any of the other ingredients of this medicine. See ‘*What are the ingredients in Xultophy<sup>®</sup>*’.
- If you think that your blood sugar is getting too low (this is called “hypoglycemia”).
- You or a member of your family has ever had medullary thyroid cancer.
- You have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- You are pregnant or breastfeeding.

As a precautionary measure,

- Always carry a spare Xultophy<sup>®</sup> and new needles with you, in case of loss or damage.
- Always carry something to show you have diabetes.
- Always carry products containing sugar with you. See the section on ‘*Low blood sugar (hypoglycemia)*’.

**To help avoid side effects and ensure proper use, talk to your healthcare professional before you take Xultophy<sup>®</sup>. Talk about any health conditions or problems you may have, including if you:**

- Or a member of your family has or has had medullary thyroid carcinoma, or if you have Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).
- Have a high heart rate (fast pulse).
- Have a condition called heart block.
- Have any heart disease, such as angina, heart rhythm disturbances or congestive heart failure; or if you have ever had a myocardial infarction (heart attack).
- Have or have had problems with your pancreas, kidneys, or liver.
- Are pregnant, or planning a pregnancy or are breastfeeding or plan to breastfeed.
- Have eye problems. Fast improvements in blood sugar control may make diabetic eye problems get worse for a short time. The long-term improvements in blood sugar control may ease the eye problems.
- Have or have had a thyroid disease.
- If you are also taking a sulphonylurea (such as glimepiride or glibenclamide), your doctor may tell you to lower your sulphonylurea dose depending on your blood sugar levels.
- The use of Xultophy® is not recommended in patients with inflammatory bowel disease or delayed gastric emptying (diabetic gastroparesis).
- If you drink alcohol (including wine and beer) your need for insulin may change as your blood sugar level may either rise or fall.
- If you have an infection, fever or have had an operation you may need more insulin than usual.
- If you suffer from diarrhea, vomiting or eat less than usual you may need less insulin than usual.
- If you exercise more than usual or if you want to change your usual diet.
- If you are ill: continue taking your insulin.
- If you go abroad: travelling over time zones may affect your insulin needs and the timing of injections. Consult your doctor if you are planning such travel.
- If you drive or use tools or machines: watch for signs of hypoglycemia. Your ability to concentrate or to react will be less during a hypoglycemic reaction. Please keep this in mind in all situations where you might put yourself and others at risk (e.g. driving a car or operating machinery). Never drive or use machinery if you feel a hypoglycemic reaction coming on.
- Have type 1 diabetes.
- Have ever had diabetic ketoacidosis (increased ketones in the blood or urine).
- Have gastrointestinal (digestive) problems.

Be especially aware of the following when using Xultophy®:

- Low blood sugar (hypoglycemia) – if your blood sugar is low, follow the advice in '*Low blood sugar (hypoglycemia)*'.
- High blood sugar (hyperglycemia) – if your blood sugar is high, follow the advice in '*high blood sugar (hyperglycemia)*'.

If you have a severe stomach ache which does not go away, tell your doctor – this could be a sign of inflamed pancreas (acute pancreatitis).

Dehydration (loss of fluids from the body) can happen if you are feeling or being sick (nausea or vomiting) or have diarrhea – it is important to drink plenty of fluids to stop dehydration.

**Other warnings you should know about:**

Before you travel, check with your physician or pharmacist on the availability of Xultophy® in other countries. If possible, bring enough Xultophy® with you on your trip.

Thiazolidinediones (class of oral antidiabetic drugs) used together with insulin may increase risk of edema and heart failure. Inform your doctor as soon as possible if you experience localized swelling (edema) or signs of heart failure such as unusual shortness of breath.

Fast improvements in blood sugar control may lead to a temporary worsening of diabetic eye disorder.

Always check the pen label before you inject your medicine to ensure that you use the correct pen.

Do not transfer Xultophy® from the pen into a syringe, as the markings on the insulin syringe will not measure the dose correctly and can result in overdosage and severe hypoglycemia.

Do not share your Xultophy® pen with another person, even if the needle is changed. Do not reuse or share needles with another person. You may give another person an infection or get an infection from them.

#### Driving and using machines

Having low or high blood sugar can affect your ability to drive or use any tools or machines. If your blood sugar is low or high, your ability to concentrate or react might be affected. This could be dangerous to yourself or others. Ask your doctor whether you can drive if:

- You often get low blood sugar.
- You find it hard to recognise low blood sugar.

#### Children and Adolescents

Do not give this medicine to children or adolescents. There is no experience with Xultophy® in children and adolescents under 18 years old.

#### **Tell your healthcare professional about all the medicines you take, including any drugs, vitamins, minerals, natural supplements or alternative medicines.**

Some medicines affect your blood sugar level – this may mean your Xultophy® dose has to change. Listed below are the most common medicines, which may affect your treatment. In particular, you should tell your doctor if you are using any medicine as mentioned below that affects your blood sugar level.

#### **Your blood sugar level may fall if you take:**

- Other medicines for diabetes (tablets or injections);
- Sulphonamides antibiotics (medicines used to treat infections);
- Anabolic steroids (used as testosterone);
- Beta-blockers (used to treat high blood pressure). They may make it harder to recognise the warning signs of low blood sugar (see *'Warning signs of low blood sugar – these may come on suddenly'*);
- Acetylsalicylic acid (and medicines called 'salicylates') – for pain and mild fever;
- Monoamine oxidase inhibitors (MAOI) (used to treat depression);

- Medicines used to treat high blood pressure and/or heart problems, such as: angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blocking (ARB) agents, disopyramide;
- A sulfonylurea medicine (such as glibenclamide or glimepiride). This is because using Xultophy® at the same time may cause your blood sugar to get too low (hypoglycemia);
- Fluoxetine;
- Fibrates (medicine used for lowering high levels of blood fats);
- Medicines used to relieve pain and lower fever, such as pentoxifylline, propoxyphene and salicylates;
- When you first start using these medicines together, your doctor may tell you to lower the dose of the sulfonylurea medicine;
- If you are not sure if the medicines you are taking contain a sulfonylurea, ask your doctor, Diabetes Nurse Educator or pharmacist;
- Octreotide (used for treatment of acromegaly (a rare illness with too much growth hormone)).

**Your blood sugar level may rise if you take:**

- Danazol (medicine acting on ovulation);
- Oral contraceptives (birth control pills);
- Growth hormone – for low levels of growth hormone;
- Sympathomimetics (such as epinephrine [adrenaline], or salbutamol, albuterol or terbutaline used to treat asthma);
- Diuretics (also called water pills), used to treat high blood pressure or fluid retention;
- Thiazides (used to treat high blood pressure or excessive fluid retention);
- Corticosteroids such as cortisone (used to treat inflammation);
- Isoniazid (used to treat tuberculosis);
- Niacin and phenothiazine;
- Hormones, such as: estrogens and/or progesterone (alone or as contraceptive pills), somatotropin, thyroid hormones, glucagon;
- Protease inhibitors (used to treat HIV infection);
- Medicines used to treat mental health problems, such as: olanzapine, clozapine;

Pioglitazone – tablets used for the treatment of type 2 diabetes mellitus. Some patients with long-standing type 2 diabetes mellitus and heart disease or previous stroke, who were treated with pioglitazone and insulin, experienced the development of heart failure. Inform your doctor straight away if you experience signs of heart failure such as unusual shortness of breath or rapid increase in weight or localised swelling (oedema).

Warfarin or other blood thinners – medicines used to prevent clotting of the blood. Tell your doctor if you are taking warfarin or other blood thinners as you might need to have blood tests more often to measure how thick your blood is (called ‘International Normalised Ratio’ or INR test).

Xultophy® with alcohol

- If you drink alcohol, your need for Xultophy® may change. Your blood sugar level may either rise or fall. You should therefore monitor your blood sugar level more often than usual.

**The following may interact with Xultophy®:**

The following list includes some, but not all, of the drugs that may increase the risk of heart

rhythm problems while receiving Xultophy<sup>®</sup>. You should check with your doctor or pharmacist before taking any other medication with Xultophy<sup>®</sup>:

- Drugs to treat hypertension.
- Drugs to treat heart failure.
- Drugs to treat HIV infection.
- Drugs to treat attention deficit-hyperactivity disorder.
- Drugs to suppress appetite/cause weight loss.
- Decongestants.
- Drugs to treat asthma.

### **How to take Xultophy<sup>®</sup>:**

Always use this medicine exactly as your doctor has told you. Check with your doctor, pharmacist or nurse if you are not sure.

Your doctor will tell you:

- How much Xultophy<sup>®</sup> you will need each day.
- When to check your blood sugar level.
- How to adjust the dose.

### How to handle Xultophy<sup>®</sup>

- Xultophy<sup>®</sup> is a pre-filled dial-a-dose pen.
- Xultophy<sup>®</sup> is administered as 'units'. The dose counter on the pen shows the number of units.
- One unit contains 1 unit of insulin degludec and 0.036 mg of liraglutide.
- The maximum daily dose of Xultophy<sup>®</sup> is 50 units (50 units of insulin degludec and 1.8 mg of liraglutide).
- Carefully read the 'Instructions on how to use' and use the pen as described.
- Always check the pen label before you inject your medicine to ensure that you use the correct pen.

### How to inject

- Before you use Xultophy<sup>®</sup> for the first time, your doctor or nurse will show you how to inject.
- Xultophy<sup>®</sup> is given as an injection under the skin (subcutaneously). Do not inject it into a vein or muscle.
- The best places to inject are the front of your thighs, upper arms or the front of your waist (abdomen).
- Change the place within the area where you inject each day to reduce the risk of developing lumps and skin pitting (see '*What are possible side effects from using Xultophy<sup>®</sup>?*').
- Detailed instructions for use are included in the '*Instructions For Use*'.

### Do not use Xultophy<sup>®</sup>

- If the pen is damaged or has not been stored correctly (see '*Storage*').
- If the liquid you can see through the pen window does not look clear and colourless.

### Use in elderly patients (65 years old or over)

Xultophy<sup>®</sup> can be used in elderly patients but if you are elderly you may need to check your blood sugar level more often. Talk to your doctor about changes in your dose.

### If you have kidney or liver problems

If you have kidney or liver problems you may need to check your blood sugar level more often.

Talk to your doctor about changes in your dose.

#### If you stop using Xultophy®

Do not stop using Xultophy® without talking to your doctor. If you stop using Xultophy® this could lead to a very high blood sugar level, see the advice in '*High blood sugar (hyperglycemia)*'.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

#### **Usual dose:**

##### Dosing time

- Use Xultophy® once each day, preferably at the same time every day. Choose a time of the day that works best for you.
- You do not have to use Xultophy® with a meal.
- Always follow your doctor's advice for dose and dose adjustment.
- If you want to change your usual diet, check with your doctor, pharmacist or nurse first as a change in diet may alter your need for Xultophy®.

#### **Overdose:**

The maximum daily dose of Xultophy® is 50 units (50 units insulin degludec and 1.8 mg liraglutide). The dose counter on the pen shows the number of units.

If you use more Xultophy® than you should, your blood sugar may get low (hypoglycemia) or you may feel or be sick (nausea or vomiting). If your blood sugar gets low, see the advice in '*Low blood sugar (hypoglycemia)*'.

If you think you have taken too much Xultophy®, contact your healthcare professional, hospital emergency department or regional Poison Control Centre immediately, even if there are no symptoms.

#### **Missed Dose:**

If you miss a dose of Xultophy®, resume your 1 time daily dosing schedule at the next scheduled dose. Do not take 2 doses at the same time or increase your dose to make up for the missed dose. If you miss more than 3 days of Xultophy®, call your healthcare professional for further instructions about taking Xultophy® at the right dose and to help lower your chance of having an upset stomach.

#### **What are possible side effects from using Xultophy®?**

Like all medicines, this medicine can cause side effects, although not everybody gets them. The following side effects may happen with this medicine:

##### Very common (may affect more than 1 in 10 people)

Too low blood sugar (Hypoglycemia): If your blood sugar level gets low you may pass out (become unconscious). Serious hypoglycemia may cause brain damage and may be life-threatening. If you have signs of low blood sugar, take actions to increase your blood sugar level straight away. See advice in '*Low blood sugar (hypoglycemia)*'.

Other side effects include:

Common (may affect up to 1 in 10 people)

- Lower appetite, feeling or being sick (nausea or vomiting), diarrhea, constipation, indigestion (dyspepsia), inflamed lining of the stomach (gastritis), stomach ache, heartburn, or bloating – these usually go away after a few days or weeks.
- Injection site reactions. The signs may include bruising, bleeding, pain, redness, hives, swelling or itching – these usually go away after a few days. See your doctor if they do not disappear after a few weeks. Stop using Xultophy<sup>®</sup> and see a doctor straight away if they become serious.
- Increase of pancreatic enzymes, such as lipase and amylase.

Uncommon (may affect up to 1 in 100 people)

- Hives.
- Allergic reactions (hypersensitivity) such as rash, itching and swelling of the face.
- Dehydration (loss of fluid from the body) – it is important to drink plenty of fluids to stop dehydration.
- Belching (eructation) and wind (flatulence).
- Rash.
- Itching.
- Skin changes where you give the injection ('lipodystrophy') – the fatty tissue under the skin may shrink ('lipoatrophy') or get thicker ('lipohypertrophy'). Changing the place where you inject each time may reduce the risk of these skin changes. If you notice these skin changes, tell your doctor or nurse. If you keep injecting in the same place, these changes can become more severe and affect the amount of medicine your body gets from the pen.
- Increased heart rate.
- Tiredness.
- Gallstones.
- Inflamed gallbladder.

Not known (frequency cannot be estimated from the available data)

- Inflamed pancreas (pancreatitis).
- Swelling of arms or legs (peripheral oedema) – when you first start using your medicine, your body may keep more water than it should. This causes swelling around your ankles and other joints. This is usually only short-lasting.
- Serious allergic reaction (anaphylactic reaction) (not known: frequency cannot be estimated from the available data).

If you have a serious allergic reaction to any of the ingredients in Xultophy<sup>®</sup>, stop using Xultophy<sup>®</sup> and see a doctor straight away. The signs of a serious allergic reaction may include:

- Local reactions (e.g. rash, redness, and itching) spread to other parts of your body.
- You suddenly feel unwell with sweating.
- You have difficulty breathing.
- You get a fast heart beat or feel dizzy.

**General effects from diabetes treatment**

*Low blood sugar (hypoglycemia)*

### Low blood sugar may happen if you

- Drink alcohol
- Exercise more than usual
- Eat too little or miss a meal
- Use too much Xultophy<sup>®</sup>

### Warning signs of low blood sugar – these may come on suddenly

Headache, slurred speech, fast heart beat, cold sweat, cool pale skin, feeling sick (nausea), feeling very hungry, shaking, feeling nervous or worried, unusually tired, weak and sleepy or confused, difficulty concentrating, short-lasting changes in your sight.

### What to do if you get low blood sugar

Eat glucose tablets or another high sugar snack – like sweets, biscuits or fruit juice (always carry glucose tablets or a high sugar snack, just in case).

- Measure your blood sugar if possible and rest. You may need to measure your blood sugar more than once. This is because improvement in your blood sugar may not happen straight away.
- Wait until the signs of low blood sugar have gone or when your blood sugar level has settled. Then carry on with your medicine as usual.

### What others need to do if you pass out

Tell everyone you spend time with that you have diabetes. Tell them what could happen if your blood sugar gets low, including the risk of passing out.

Let them know that if you pass out, they must:

- Turn you on your side
- Get medical help straight away
- Not give you any food or drink – because you may choke

You may recover more quickly from passing out with an injection of glucagon. This can only be given by someone who knows how to use it.

- If you are given glucagon you will need sugar or a sugary snack as soon as you come round.
- If you do not respond to a glucagon injection, you will have to be treated in a hospital.
- If severe low blood sugar is not treated over time, it can cause brain damage. This can be short- or long-lasting. It may even cause death.

### Talk to your doctor if

- Your blood sugar got so low that you passed out
- You have had an injection of glucagon
- You have had low blood sugar a few times recently

This is because the dosing of your Xultophy<sup>®</sup> injections, food or exercise may need to be changed.

### *High blood sugar (hyperglycemia)*

### High blood sugar may happen if you

- Drink alcohol
- Exercise less than usual

- Eat more than usual
- Get an infection or a fever
- Have not used enough Xultophy<sup>®</sup>, keep using less Xultophy<sup>®</sup> than you need, forget to use Xultophy<sup>®</sup> or stop using Xultophy<sup>®</sup> without talking to your doctor

Warning signs of high blood sugar – these normally appear gradually

Flushed, dry skin, feeling sleepy or tired, dry mouth, fruity (acetone) breath, urinating more often, feeling thirsty, losing your appetite, feeling or being sick (nausea or vomiting). These may be signs of a very serious condition called ‘ketoacidosis’. This is a build-up of acid in the blood because the body is breaking down fat instead of sugar. If not treated, this could lead to diabetic coma and eventually death.

What to do if you get high blood sugar

- Test your blood sugar level
- Test your urine for ketones
- Get medical help straight away

These are not all the possible side effects you may feel when taking Xultophy<sup>®</sup>. If you experience any side effects not listed here, contact your healthcare professional. Please also see Warnings and Precautions.

<b>Serious side effects and what to do about them</b>			
Symptom / effect	Talk to your healthcare professional		Stop taking drug and get immediate medical help
	Only if severe	In all cases	
<b>COMMON</b> Hypoglycemia (low blood sugar) symptoms: feeling confused, fits and passing out.		√	√
Gastrointestinal disorders such as Nausea, vomiting, dyspepsia and constipation		√	
Reaction at injection site		√	
<b>UNCOMMON</b> Increased Heart Rate, chest pain or symptoms of possible heart rhythm disturbance/dizziness, palpitations, fainting or seizures		√	√
Changes under the skin where you use the injection (lipodystrophy)		√	
<b>UNKNOWN</b> Severe form of allergic reaction (anaphylactic reaction) with symptoms of breathing problems, swelling of throat and face, and fast heart beat. You should seek immediate medical attention		√	√
Pancreatitis / persistent, severe abdominal pain (stomach area) which might reach through your back, as well as nausea with or without vomiting		√	√
Low potassium in your blood (hypokalemia)		√	√
Kidney problems (kidney failure). In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems to get worse.		√	√
Thyroid tumour / lump in the neck, difficulty in swallowing difficulty in breathing or persistent hoarseness		√	

If you have a troublesome symptom or side effect that is not listed here or becomes bad enough to interfere with your daily activities, talk to your healthcare professional.

## Reporting Side Effects

You can report any suspected side effects associated with the use of health products to Health Canada by:

- Visiting the Web page on **Adverse Reaction Reporting** (<http://www.hc-sc.gc.ca/dhpmpps/medeff/report-declaration/index-eng.php>) for information on how to report online, by mail or by fax; or
- Calling toll-free at 1-866-234-2345.

*NOTE: Contact your health professional if you need information about how to manage your side effects. The Canada Vigilance Program does not provide medical advice.*

## Storage

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the pen label and carton after 'EXP'. The expiry date refers to the last day of that month.

## Before opening

Store in a refrigerator (2°C to 8°C). Keep away from the freezing element. Do not freeze.

## During use

Do not freeze. You can carry Xultophy® with you and keep it at room temperature (no more than 30°C) or in a refrigerator (2°C to 8°C) for up to 21 days. The product should be thrown away 21 days after first opening.

Always keep the cap on the pre-filled pen when you are not using it in order to protect it from light.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## If you want more information about Xultophy®

- Talk to your healthcare professional.
- Find the full product monograph that is prepared for healthcare professionals and includes this Patient Medication Information by visiting the Health Canada website (<http://hc-sc.gc.ca/index-eng.php>); the Novo Nordisk website ([www.novonordisk.ca](http://www.novonordisk.ca)), or by calling Novo Nordisk Canada Inc., at 1-800-465-4334.

This leaflet was prepared by Novo Nordisk Canada Inc.

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## INSTRUCTIONS FOR USE

### Instructions on how to use Xultophy® 100 units/mL + 3.6 mg/mL solution for injection

**Please read these instructions carefully** before using your Xultophy® pre-filled pen. **Do not use the pen without proper training** from your doctor or nurse.

Start by checking your pen to **make sure that it contains Xultophy® 100 units/mL + 3.6 mg/mL**, then look at the illustrations below to get to know the different parts of your pen and needle.

**If you are blind or have poor eyesight and cannot read the dose counter on the pen, do not use this pen without help.** Get help from a person with good eyesight who is trained to use the Xultophy® pre-filled pen.

**Xultophy® is a medicine that contains insulin degludec and liraglutide. Xultophy® is administered as ‘units’.** One unit contains 1 unit insulin degludec + 0.036 mg liraglutide.

Your pen is a pre-filled dial-a-dose pen. It contains 3 mL of Xultophy® solution. It delivers doses from:

- 1 unit
- to a **maximum of 50 units** (50 units insulin degludec + 1.8 mg liraglutide)

Your pen delivers doses in increments of 1 unit.

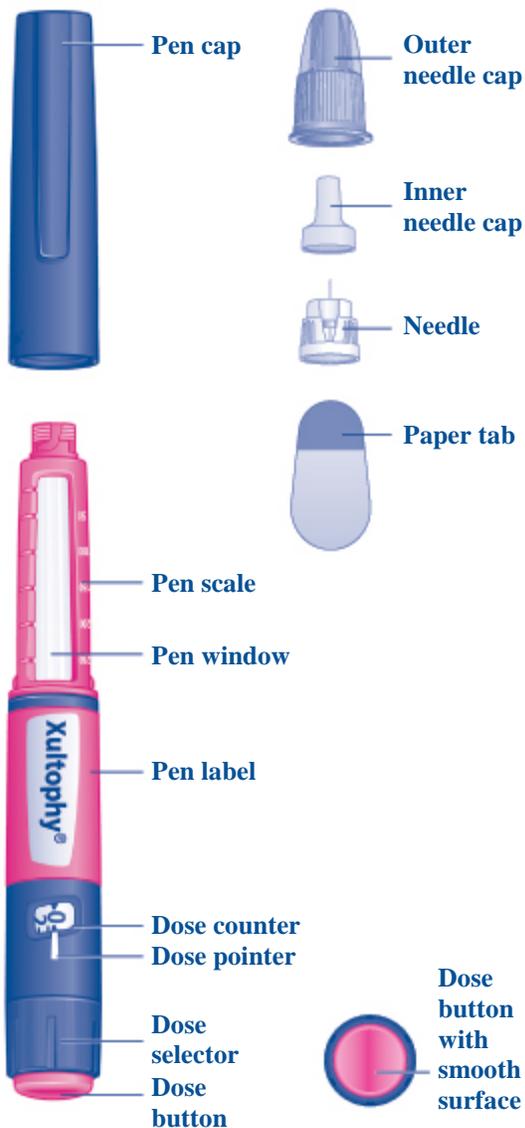
Do not do any conversion of your dose. The units dialed equal the number shown in the dose counter.

Your pen is recommended to be used with NovoTwist® or NovoFine® disposable needles up to a length of 8 mm and as thin as 32G. Needles are not included in the pack.

#### **Important information**

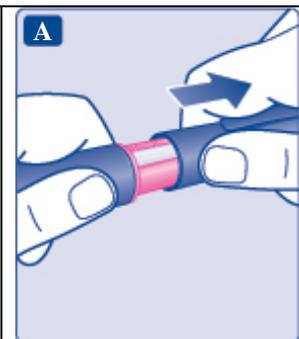
Pay special attention to these notes as they are important for safe use of the pen.

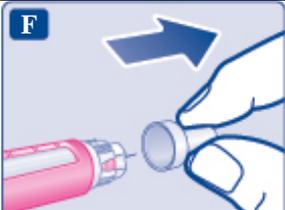
**Xultophy® pre-filled pen and needle (example)**

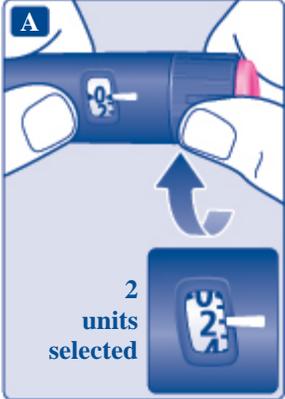
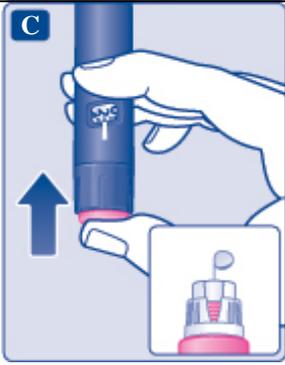


**1 Prepare your pen with a new needle**

- **Check the name and coloured label** of your pen, to make sure that it contains Xultophy®. This is especially important if you take more than one type of injectable medicine. Taking the wrong medicine could be harmful to your health.
- **Pull off the pen cap.**



<ul style="list-style-type: none"> <li>• <b>Check that the solution in your pen is clear</b> and colourless. Look through the pen window. If the solution looks cloudy, do not use the pen.</li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Take a new needle</b>, and tear off the paper tab.</li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Push the needle straight onto the pen. Turn until it is on tight.</b></li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Pull off the outer needle cap and keep it for later.</b> You will need it after the injection, to safely remove the needle from the pen.</li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Pull off the inner needle cap and throw it away.</b> If you try to put it back on, you may accidentally stick yourself with the needle. A drop of solution may appear at the needle tip. This is normal, but you must still check the flow. <b>Do not attach a new needle</b> to your pen until you are ready to take your injection.</li> </ul> <p>⚠ <b>Always use a new needle for each injection.</b> This may prevent blocked needles, contamination, infection and inaccurate dosing.</p> <p>⚠ <b>Never use a bent or damaged needle.</b></p>	

<p><b>2 Check the flow</b></p> <ul style="list-style-type: none"> <li>• Turn the dose selector to <b>select 2 units</b>. Make sure the dose counter shows 2.</li> <li>• The dose counter and the dose pointer show how many units of Xultophy® you select.</li> </ul>	
<ul style="list-style-type: none"> <li>• Hold the pen with the needle pointing up. <b>Tap the top of the pen gently</b> a few times to let any air bubbles rise to the top.</li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Press and hold in the dose button</b> until the dose counter returns to 0. The 0 must line up with the dose pointer. A drop of solution should appear at the needle tip.</li> </ul> <p>A small drop may remain at the needle tip, but it will not be injected.</p> <p><b>If no drop appears</b>, repeat steps <b>2A</b> to <b>2C</b> up to 6 times. If there is still no drop, change the needle and repeat steps <b>2A</b> to <b>2C</b> once more.</p> <p><b>If a drop of solution still does not appear</b>, dispose of the pen and use a new one.</p> <p><b>⚠ Always make sure that a drop appears</b> at the needle tip before you inject. This makes sure that the solution flows. If no drop appears, you will <b>not</b> inject any medicine, even though the dose counter may move. <b>This may indicate a blocked or damaged needle.</b></p> <p><b>⚠ It is important always to check the flow before you inject.</b> If you do not check the flow, you may get too little medicine, or no medicine at all. This may lead to high blood sugar level.</p>	

### 3 Select your dose

- **Turn the dose selector to select the dose you need.**

The dose counter shows the dose in units.

If you select a wrong dose, you can turn the dose selector forwards or backwards to the correct dose.

The pen can dial up to a maximum of 50 units.

The dose selector changes the number of units.  
Only the dose counter and dose pointer will show how many units you select per dose.

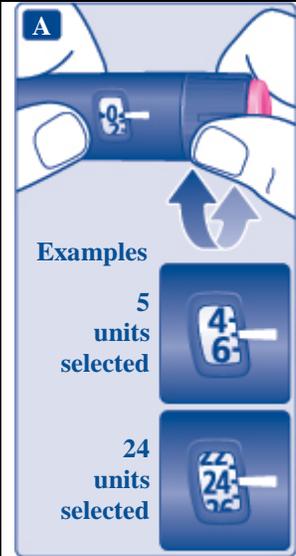
You can select up to 50 units per dose. When your pen contains less than 50 units, the dose counter stops at the number of dose steps left.

The dose selector clicks differently when turned forwards, backwards or past the number of units left. Do not count the pen clicks.

- ⚠ **Always use the dose counter and the dose pointer to see how many units you have selected before injecting the medicine.**

Do not count the pen clicks. If you select and inject the wrong dose, your blood sugar level may get high or low.

Do not use the pen scale, it only shows approximately how much solution is left in your pen.



#### How much solution is left?

- The **pen scale** shows you **approximately** how much solution is left in your pen.

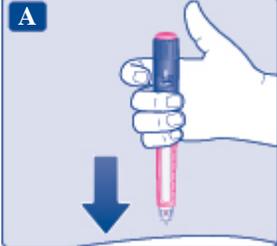
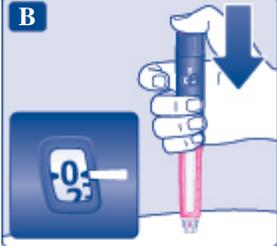
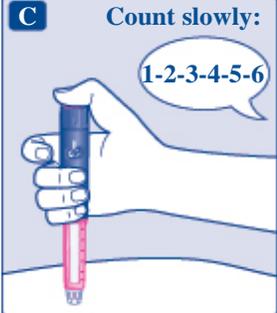


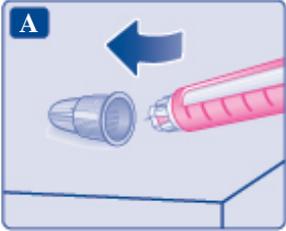
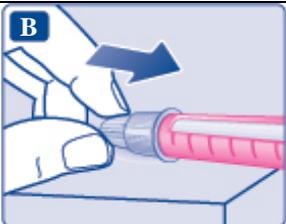
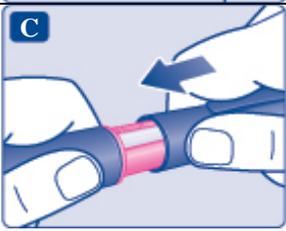
- **To see precisely how much solution is left, use the dose counter:**  
Turn the dose selector until the **dose counter stops**.  
If it shows 50, **at least 50** units are left in your pen. If it shows **less than 50**, the number shown is the number of units left in your pen.

If you need more medicine than what is left in your pen, you can split your dose between two pens.

- ⚠ **Be very careful to calculate correctly if splitting your dose.**  
If in doubt, take the full dose with a new pen. If you split the dose wrongly, you will inject too little or too much medicine. This may make your blood sugar level high or low.



<p><b>4 Inject your dose</b></p> <ul style="list-style-type: none"> <li>• <b>Insert the needle into your skin</b> as your doctor or nurse has shown you.</li> <li>• <b>Make sure you can see the dose counter.</b> Do not cover it with your fingers. This could interrupt the injection.</li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Press and hold down the dose button until the dose counter shows 0.</b> The 0 must line up with the dose pointer. You may then hear or feel a click.</li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Keep the needle in your skin after</b> the dose counter has returned to 0 and <b>count slowly to 6.</b></li> <li>• If the needle is removed earlier, you may see a stream of solution coming from the needle tip. If so, the full dose will not be delivered, and you should increase the frequency of checking your blood sugar level.</li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Remove the needle from your skin.</b> If blood appears at the injection site, press lightly. Do not rub the area.  You may see a drop of solution at the needle tip after injecting. This is normal and does not affect your dose.</li> </ul> <p><b>⚠ Always watch the dose counter to know how many units you inject.</b> Hold the dose button down until the dose counter shows 0. If the dose counter does not return to 0, the full dose has not been delivered, which may lead to high blood sugar level.</p> <p><b>How to identify a blocked or damaged needle?</b></p> <ul style="list-style-type: none"> <li>• If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.</li> <li>• In this case - you have <b>not</b> received <b>any</b> medicine - even though the dose counter has moved from the original dose that you have set.</li> </ul> <p><b>How to handle a blocked needle?</b> Change the needle as described in section 5 and repeat all steps starting with section 1: Prepare your pen with a new needle. Make sure you select the full dose you need.</p>	

<p><b>Never touch the dose counter when you inject.</b> This can interrupt the injection.</p>	
<p><b>5 After your injection</b></p> <ul style="list-style-type: none"> <li>• <b>Lead the needle tip into the outer needle cap</b> on a flat surface without touching the needle or the outer cap.</li> </ul>	
<ul style="list-style-type: none"> <li>• Once the needle is covered, <b>carefully push the outer needle cap completely on.</b></li> <li>• <b>Unscrew the needle</b> and dispose of it carefully as instructed by your doctor or nurse.</li> </ul>	
<ul style="list-style-type: none"> <li>• <b>Put the pen cap on</b> your pen after each use to protect the solution from light.</li> </ul> <p><b>Always dispose of the needle after each injection</b> to ensure the use of a sharp needle and prevent blocked needles. If the needle is blocked, you will <b>not</b> inject any medicine.</p> <p>When the pen is empty, throw it away <b>without</b> a needle on as instructed by your doctor, nurse, pharmacist or local authorities.</p> <p><b>⚠ Never try to put the inner needle cap back on the needle.</b> You may stick yourself with the needle.</p> <p><b>⚠ Always remove the needle from your pen after each injection.</b> This may prevent blocked needles, contamination, infection, leakage of solution and inaccurate dosing.</p>	
<p><b>⚠ Further important information</b></p> <ul style="list-style-type: none"> <li>• <b>Always keep an extra pen and new needles</b>, in case of loss or damage.</li> <li>• Always keep your pen and needles <b>out of sight and reach of others</b>, especially children.</li> <li>• <b>Never share your pen</b> with other people. Your medicine might be harmful to their health.</li> <li>• <b>Never share your needles</b> with other people. It might lead to cross-infection.</li> <li>• Caregivers must <b>be very careful when handling used needles</b> – to prevent needle injury and cross-infection.</li> </ul>	
<p><b>Caring for your pen</b></p> <ul style="list-style-type: none"> <li>• <b>Do not leave the pen in a car</b> or other place where it can get too hot or too cold.</li> <li>• <b>Do not store your pen at temperatures above 30°C.</b></li> <li>• <b>Do not expose your pen to dust, dirt or liquid.</b></li> <li>• <b>Do not wash, soak or lubricate your pen.</b> If necessary, clean it with mild detergent on a moistened cloth.</li> <li>• <b>Do not drop your pen</b> or knock it against hard surfaces. If you drop it or suspect a problem, attach a new needle and check the flow before you inject.</li> <li>• <b>Do not try to refill your pen.</b> Once empty, it must be disposed of.</li> </ul>	

- **Do not try to repair your pen or pull it apart.**