

Xultophy 100 units/mL + 3.6 mg/mL Solution for Injection

Insulin degludec + Liraglutide

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1. What Xultophy® is used for

Xultophy® is used 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.

2. How Xultophy® works

Xultophy® 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.
- liraglutide - a 'GLP-1 analogue' that helps your body make more insulin during meals and lowers the amount of sugar made by your body.

Xultophy® and oral medicines for diabetes

Xultophy® is used with oral medicines for diabetes (such as metformin, pioglitazone and sulfonylurea medicines). It is prescribed when these medicines

(used alone or with GLP-1 treatment or with basal insulin) are not enough to control your blood sugar levels.

If you use GLP-1 treatment

You should stop your GLP-1 treatment prior to starting on Xultophy®.

If you use insulin

You should stop your insulin treatment prior to starting on Xultophy®.

3. Before you use Xultophy®

- When you must not use it

Do not use Xultophy®

- if you are allergic to insulin degludec or liraglutide or any of the other ingredients of this medicine (listed in section 8 *Product Description*).

- Before you start to use it

Warnings and precautions

Talk to your doctor, pharmacist or nurse before using Xultophy®.

- If you are also taking a sulfonylurea (such as glimepiride or glibenclamide), your doctor may tell you to lower your sulfonylurea dose depending on your blood sugar levels.
- Do not use Xultophy® if you have type 1 diabetes mellitus or if you have 'ketoacidosis' (a condition with a build-up of acid in the blood).
- The use of Xultophy® is not recommended in patients with inflammatory bowel disease or delayed gastric emptying (diabetic gastroparesis).
- If you know that you are due to have surgery where you will be under anaesthesia (sleeping), please tell your doctor that you are taking

Xultophy®.

Be especially aware of the following when using Xultophy®:

- low blood sugar (hypoglycaemia) - if your blood sugar is low, follow the advice in section 6, *Low blood sugar (hypoglycaemia)*.
- high blood sugar (hyperglycaemia) - if your blood sugar is high, follow the advice in section 6, *High blood sugar (hyperglycaemia)*.
- Ensuring you use the right medicine - Always check the pen label before each injection to avoid accidentally confusing Xultophy® with other products.

Important things to know before you use this medicine

Tell your doctor if you:

- 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.

Important things to know while you are using this medicine

- 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 diarrhoea - it is important to drink plenty of fluids to stop dehydration.

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Skin changes at the injection site

The injection site should be rotated to help prevent changes to the fatty tissue under the skin, such as skin thickening, skin shrinking or lumps under the skin. The insulin may not work very well if you inject into a lumpy, shrunken or thickened area (see section 4 *How to use Xultophy*[®]). Tell your doctor if you notice any skin changes at the injection site. Tell your doctor if you are currently injecting into these affected areas before you start injecting in a different area. Your doctor may tell you to check your blood sugar more closely, and to adjust your insulin or your other antidiabetic medications dose.

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.

- Taking other medicines

Tell your doctor, pharmacist or nurse if you are taking, have recently taken or might take any other 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 Xultophy[®] treatment.

Your blood sugar level may fall if you take:

- other medicines for diabetes (tablets or injections)
- sulfonamides - for infections
- anabolic steroids - such as testosterone
- beta-blockers - for high blood pressure. They may make it harder to recognise the warning signs of low blood

sugar (see section 6, *Warning signs of low blood sugar - these may come on suddenly*)

- acetylsalicylic acid (and medicines called 'salicylates') - for pain and mild fever
- monoamine oxidase (MAO) inhibitors - for depression
- angiotensin converting enzyme (ACE) inhibitors - for some heart problems or high blood pressure.

Your blood sugar level may rise if you take:

- danazol - medicine affecting ovulation
- oral contraceptives - birth control pills
- thyroid hormones - for thyroid disease
- growth hormone - for low levels of growth hormone
- medicines called 'glucocorticoids' such as cortisone - for inflammation
- medicines called 'sympathomimetics' such as epinephrine (adrenaline), salbutamol or terbutaline - for asthma
- water tablets called 'thiazides' - for high blood pressure or if your body is holding on to too much water (water retention).

Octreotide and lanreotide - used for treatment of acromegaly (a rare illness with too much growth hormone). They may increase or decrease your blood sugar level.

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).

4. How to use Xultophy[®]

- How much to use

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

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.

Your doctor will tell you

- how much Xultophy[®] you will need each day
- when to check your blood sugar level
- how to adjust the dose.

Your dose of Xultophy[®] is administered as 'dose steps'. The dose counter on the pen shows the number of dose steps.

- When to use it

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.
- If it is not possible to use

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Xultophy® at the same time every day, it can be used at a different time of the day. Make sure to have a minimum of 8 hours between the doses.

- 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®.

How to handle Xultophy®

Xultophy® is a pre-filled dial-a-dose pen.

- Xultophy® is administered as 'dose steps'. The dose counter on the pen shows the number of dose steps.
- One dose step contains 1 unit of insulin degludec and 0.036 mg of liraglutide.
- The maximum daily dose of Xultophy® is 50 dose steps (50 units of insulin degludec and 1.8 mg of liraglutide).

Carefully read the *Instructions on how to use Xultophy®* 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® for the first time, your doctor or nurse will show you how to inject.

- Xultophy® 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 section 6 *Side effects*).

- Always use a new needle for each injection. Re-use of needles may increase the risk of blocked needles leading to inaccurate dosing. Dispose of the needle safely after each use.
- Do not use a syringe to remove the solution from the pen to avoid dosing errors and potential overdose.

Detailed instructions for use are included in the *Instructions on how to use Xultophy®*.

Do not use Xultophy®

- if the pen is damaged or has not been stored correctly (see section 7 *Storage and disposal of Xultophy®*)
- 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® 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.

- How long to use it

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 section 6, *High blood sugar (hyperglycaemia)*.

If you have any further questions on the use of this medicine, ask your

doctor, pharmacist or nurse.

- If you forget to use it

If you forget a dose, inject the missed dose when discovering the mistake, ensuring a minimum of 8 hours between doses. If you discover that you missed your previous dose when it is time to take your next regular scheduled dose, do not take a double dose.

- If you use too much (overdose)

If you use more Xultophy® than you should, your blood sugar may get low (hypoglycaemia) or you may feel or be sick (nausea or vomiting). If your blood sugar gets low, see the advice in section 6, *Low blood sugar (hypoglycaemia)*.

5. While you are using it

- Things you must do

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

- Things you must not do

Do not stop using this medicine without talking to your doctor.

- Things to be careful of

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.

Pregnancy and breast-feeding

Do not use Xultophy® if you are pregnant or plan to become pregnant. Tell your doctor if you are pregnant, think you might be pregnant or are planning to have a baby. It is not known if Xultophy® affects the baby.

Do not use Xultophy® if you are

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breast-feeding. It is not known if Xultophy® passes into breast milk.

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.

Important information about some of the ingredients of Xultophy®

Xultophy® contains less than 1 mmol sodium (23 mg) per dose, i.e., it is essentially 'sodium-free'.

6. Side effects

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

- **Low blood sugar** (very common: may affect more than 1 in 10 people).
If your blood sugar level gets low you may pass out (become unconscious). Serious hypoglycaemia 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 (hypoglycaemia)*' further down in this section.
- **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®, stop using Xultophy® and see a doctor straight away. The *signs of a serious allergic reaction* are:

- local reactions spread to other parts of your body
- you suddenly feel unwell with sweating
- you have difficulty breathing
- you get a fast heartbeat or feel dizzy.

Skin changes at the injection site:

If you inject insulin at the same place, the fatty tissue may shrink (lipoatrophy) or thicken (lipohypertrophy) (may affect up to 1 in 100 people). Lumps under the skin may also be caused by build-up of a protein called amyloid (cutaneous amyloidosis; how often this occurs is not known). The insulin may not work very well if you inject into a lumpy, shrunken or thickened area. Change the injection site with each injection to help prevent these skin changes.

Other side effects

Common (may affect up to 1 in 10 people)

- Dizziness.
- Lower appetite, feeling or being sick (nausea or vomiting), diarrhoea, 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® 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 (red bumps on your skin that are sometimes itchy).
- 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.
- Increased heart rate.
- Gallstones.
- Inflamed gallbladder.
- Change in how things taste.

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

- Inflamed pancreas (pancreatitis).
- Delay in the emptying of the stomach.
- 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.
- Bowel obstruction. A severe form of constipation with additional symptoms such as stomach ache, bloating,

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vomiting etc.

General effects from diabetes treatment

► **Low blood sugar (hypoglycaemia)**

Low blood sugar may happen if you:

- drink alcohol
- exercise more than usual
- eat too little or miss a meal
- use too much Xultophy®.

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

Headache, slurred speech, fast heartbeat, 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 if you receive 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 glucagon treatment, 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 used glucagon
- you have had low blood sugar a few times recently.

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

► **High blood sugar (hyperglycaemia)**

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®, keep using less

Xultophy® than you need, forget to use Xultophy® or stop using Xultophy® 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 blood or urine for ketones.
- Get medical help straight away.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]. By reporting side effects you can help provide more information on the safety of this medicine.

7. Storage and disposal of Xultophy®

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- **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 'Expiry'. The expiry date refers to the last day of that month.

Before opening

Store in a refrigerator (2 °C - 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 - 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.

- **Disposal**

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.

8. Product description

- **What it looks like**

Xultophy® is a clear and colourless solution.

Pack sizes of 1, 3 and 5 pens of 3 mL. Not all pack sizes may be marketed.

- **Ingredients**

- **Active ingredient**

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.

- **Inactive ingredients**

Glycerol, phenol, zinc acetate, hydrochloric acid and sodium hydroxide (for pH adjustment), and water for injections.

- **MAL number**

MAL22096008AZ

9. Manufacturer

Novo Nordisk A/S
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DK-2880 Bagsværd
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10. Product Registration Holder

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