

Package leaflet: Information for the patient

## Xultophy® 100 units/mL + 3.6 mg/mL solution for injection

(insulin degludec + liraglutide)

**Read all of this leaflet carefully before you start using this medicine because it contains important information for you.**

- 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 section 4.

### What is in this leaflet

1. What Xultophy is and what it is used for
2. What you need to know before you use Xultophy
3. How to use Xultophy
4. Possible side effects
5. How to store Xultophy
6. Contents of the pack and other information

## 1. What Xultophy is and what it is used for

### 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.

### 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.

## 2. What you need to know before you use Xultophy

### 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 6).

### 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 4 ‘Low blood sugar (hypoglycaemia)’.
- high blood sugar (hyperglycaemia) – if your blood sugar is high, follow the advice in section 4 ‘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.

### 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 3 ‘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.

### Other medicines and Xultophy

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 4 ‘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 onto 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).

### 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 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’.

## 3. How to use Xultophy

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.

### 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 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’ on the other side of this leaflet 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 4).
- 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 on the other side of this leaflet.

### Do not use Xultophy:

- If the pen is damaged or has not been stored correctly (see section 5).
- 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.

#### If you use more Xultophy than you should

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 4 'Low blood sugar (hypoglycaemia)'.

#### If you forget to use Xultophy

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 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 section 4 'High blood sugar (hyperglycaemia)'.

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

## 4. Possible 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 include:

**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, 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 can also report side effects directly via: Yellow Card Scheme Website: [www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the **Google Play** or **Apple App Store**.

By reporting side effects, you can help provide more information on the safety of this medicine.

## 5. How to store Xultophy

**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.

If this medicine shows any sign of discolouration or deterioration, you should seek the advice of your pharmacist who will tell you what to do.

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.

## 6. Contents of the pack and other information

**What Xultophy contains**

- 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.
- The other ingredients are glycerol, phenol, zinc acetate, hydrochloric acid and sodium hydroxide (for pH adjustment), and water for injections. See also section 2 'Important information about some of the ingredients of Xultophy' for information on sodium.

**What Xultophy looks like and contents of the pack**

Xultophy is a clear and colourless solution.

Pack size of 3 pens of 3 mL.

**Manufacturer**

Novo Nordisk A/S

Novo Allé

DK-2880 Bagsværd, Denmark

Procured from within the EU.

Repackaged by the Product Licence Holder:

Cross Healthcare Ltd., Unit 2a, Bandedeath Industrial Estate,

Throsk, Stirling,

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United Kingdom.

Xultophy 100 units/mL + 3.6 mg/mL solution for injection

PL 20504/0423

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**Please see separate sheet for instructions on how to use your pre-filled pen.**

**This leaflet was last revised in 17/01/2025**

## Blind or partially sighted? Is this leaflet hard to see or read? Call 01786-817707 (Regulatory department), to obtain the leaflet in a format suitable for you.

## 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 'dose steps'.** One dose step 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 dose step
- to a **maximum of 50 dose steps** (50 units insulin degludec + 1.8 mg liraglutide)

Your pen delivers doses in increments of 1 dose step. Do not do any conversion of your dose. The dose steps dialled equal the number shown in the dose counter.

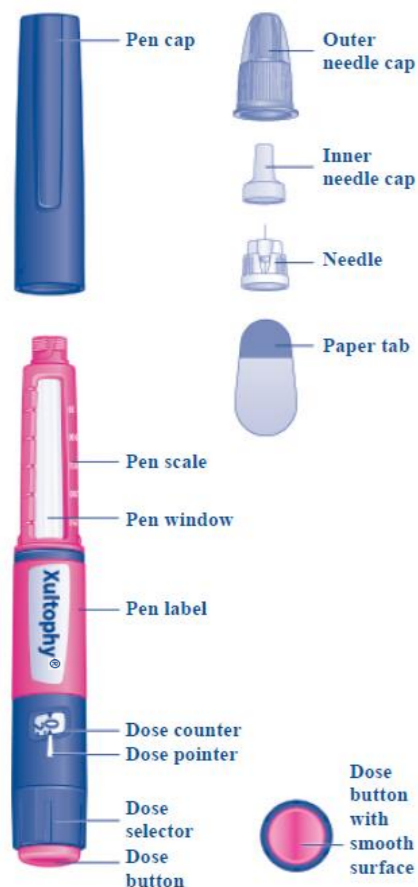
Your pen is designed to be used with NovoTwist or NovoFine disposable needles up to a length of 8 mm and as thin as 32G. Needles are not included in the pack.



### Important information

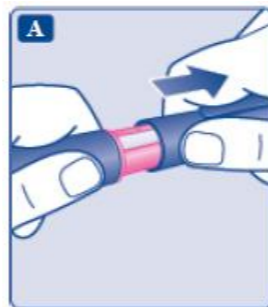
Pay special attention to these notes as they are important for safe use of the pen.

### Xultophy pre-filled pen and needle (example)

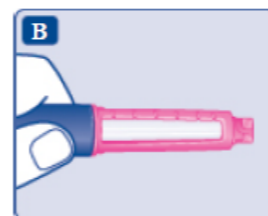


## 1 Prepare your pen with a new needle

- **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.**



- **Check that the solution in your pen is clear** and colourless. Look through the pen window. If the solution looks cloudy, do not use the pen.



- **Take a new needle,** and tear off the paper tab.



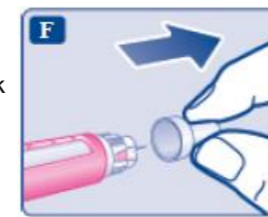
- **Push the needle straight onto the pen.** Turn until it is on tight.



- **Pull off the outer needle cap and keep it for later.** You will need it after the injection, to safely remove the needle from the pen.



- **Pull off the inner needle cap and throw it away.** 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. **Do not attach a new needle** to your pen until you are ready to take your injection.



**Always use a new needle for each injection.** This may prevent blocked needles, contamination, infection and inaccurate dosing.



**Never use a bent or damaged needle.**

## 2 Check the flow

- Turn the dose selector to **select 2 dose steps.** Make sure the dose counter shows 2.
- The dose counter and the dose pointer show how many dose steps of Xultophy you select.



- Hold the pen with the needle pointing up. **Tap the top of the pen gently** a few times to let any air bubbles rise to the top.



- **Press and hold in the dose button** 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.



A small drop may remain at the needle tip, but it will not be injected.

**If no drop appears,** repeat steps 2A to 2C up to 6 times. If there is still no drop, change the needle and repeat steps 2A to 2C once more.

**If a drop of solution still does not appear,** dispose of the pen and use a new one.



**Always make sure that a drop appears** at the needle tip before you inject. This makes sure that the solution flows. If no drop appears, you will **not** inject any medicine, even though the dose counter may move. **This may indicate a blocked or damaged needle.**



**It is important always to check the flow before you inject.** 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.

## 3 Select your dose

- **Turn the dose selector to select the dose you need.** The dose counter shows the dose in dose steps. If you select a wrong dose, you can turn the dose selector forward or backward to the correct dose. The pen can dial up to a maximum of 50 dose steps.



The dose selector changes the number of dose steps. Only the dose counter and dose pointer will show how many dose steps you select per dose. You can select up to 50 dose steps per dose. When your pen contains less than 50 dose steps, the dose counter stops at the number of dose steps left. The dose selector clicks differently when turned forward, backward or past the number of dose steps left. Do not count the pen clicks.

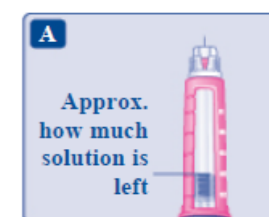


**Always use the dose counter and the dose pointer to see how many dose steps you have selected before injecting the medicine.**

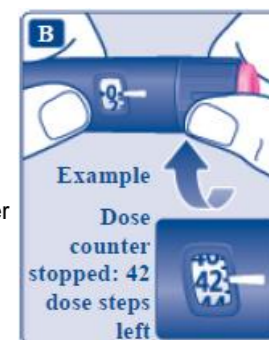
Do not count the pen clicks. If you select and inject the wrong dose, your blood sugar level may get high or low. Do not use the pen scale, it only shows approximately how much solution is left in your pen.

### 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** dose steps are left in your pen. If it shows **less than 50,** the number shown is the number of dose steps left in your pen.



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

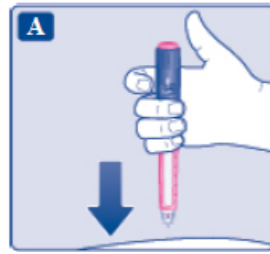


**Be very careful to calculate correctly if splitting your dose.**

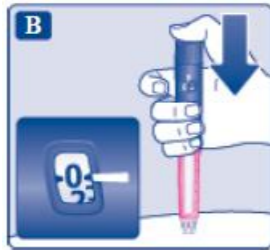
If in doubt, take the full dose with a new pen. If you split the dose wrongly, you will inject too little or too much medicine. This may make your blood sugar level high or low.

#### 4 Inject your dose

- **Insert the needle into your skin** as your doctor or nurse has shown you.
- **Make sure you can see the dose counter.** Do not cover it with your fingers. This could interrupt the injection.



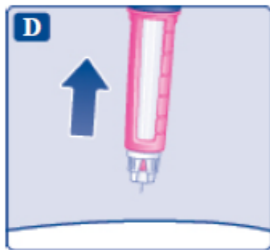
- **Press and hold down the dose button until the dose counter shows 0.** The 0 must line up with the dose pointer. You may then hear or feel a click.



- **Keep the needle in your skin** after the dose counter has returned to 0 and **count slowly to 6.**
- 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.



- **Remove the needle from your skin.** 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.

- ⚠ **Always watch the dose counter to know how many dose steps you inject.** 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.

##### How to identify a blocked or damaged needle?

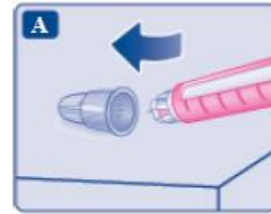
- If 0 does not appear in the dose counter after continuously pressing the dose button, you may have used a blocked or damaged needle.
- In this case - you have **not** received **any** medicine – even though the dose counter has moved from the original dose that you have set.

##### How to handle a blocked needle?

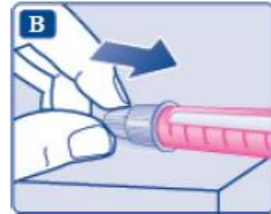
Change the needle as described in section 5 and repeat all steps starting with section 1: Prepare your pen with a new needle. Make sure you select the full dose you need. **Never touch the dose counter when you inject.** This can interrupt the injection.

#### 5 After your injection

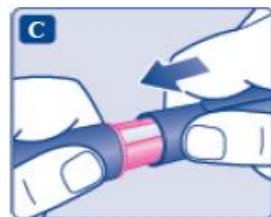
- **Lead the needle tip into the outer needle cap** on a flat surface without touching the needle or the outer cap.



- Once the needle is covered, **carefully push the outer needle cap completely on.**
- **Unscrew the needle** and dispose of it carefully as instructed by your doctor or nurse.



- **Put the pen cap on** your pen after each use to protect the solution from light.



**Always dispose of the needle after each injection** to ensure the use of a sharp needle and prevent blocked needles. If the needle is blocked, you will **not** inject any medicine.

When the pen is empty, throw it away **without** a needle on as instructed by your doctor, nurse, pharmacist or local authorities.

- ⚠ **Never try to put the inner needle cap back on the needle.** You may stick yourself with the needle.

- ⚠ **Always remove the needle from your pen after each injection.** This may prevent blocked needles, contamination, infection, leakage of solution and inaccurate dosing.

#### ⚠ Further important information

- **Always keep an extra pen and new needles,** in case of loss or damage.
- Always keep your pen and needles **out of sight and reach of others,** especially children.
- **Never share your pen** with other people. Your medicine might be harmful to their health.
- **Never share your needles** with other people. It might lead to cross-infection.
- Caregivers must **be very careful when handling used needles** – to prevent needle injury and cross-infection.

#### Caring for your pen

- **Do not leave the pen in a car** or other place where it can get too hot or too cold.
- **Do not store your pen at temperatures above 30°C.**
- **Do not expose your pen to dust, dirt or liquid.**
- **Do not wash, soak or lubricate your pen.** If necessary, clean it with mild detergent on a moistened cloth.
- **Do not drop your pen** 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.
- **Do not try to refill your pen.** Once empty, it must be disposed of.
- **Do not try to repair your pen** or pull it apart.

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