

**Patient leaflet in accordance with the Pharmacists' Regulations
(Preparations) - 1986**

This medicine is dispensed with a doctor's prescription only

Xultophy®

Solution for injection under the skin

Active ingredients: insulin degludec 100 U/mL + liraglutide 3.6 mg/mL

Inactive ingredients and allergens in this medicine: See section 2 under 'Important information about some of this medicine's ingredients' and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine.

If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar to yours.

1. What is this medicine intended for?

Xultophy is intended for the treatment of adults with uncontrolled type 2 diabetes mellitus to improve control of blood sugar level in addition to diet and exercise along with other oral medicines for diabetes.

Therapeutic group:

Medicines used to treat diabetes. Long-acting insulins and analogues for injection.

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 contains two active ingredients that help your body control your blood sugar:

- insulin degludec - a long-acting basal insulin which helps lower 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 is given with oral medicines for diabetes (such as metformin, pioglitazone and sulfonylurea medicines) 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:

You should stop your GLP-1 treatment before starting treatment with Xultophy.

If you use insulin:

You should stop your insulin treatment before starting treatment with Xultophy.

2. Before using this medicine

Do not use this medicine if:

You are sensitive (allergic) to insulin degludec or liraglutide or to any of the other ingredients in this this medicine (see section 6 'Additional information').
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Special warnings about using this medicine

Tell to your doctor before using Xultophy:

- If you are also taking sulfonylurea medicines (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 have eye problems. Fast improvements in control of your blood sugar may make diabetic eye problems get worse for a short time. The long-term improvements in blood sugar control may ease the eye problems.
- If you have or have had thyroid disease.

Be especially aware of the following conditions when using Xultophy:

- low blood sugar (hypoglycaemia) - if your blood sugar is low, follow the instructions in section 4 'Low blood sugar (hypoglycaemia)'.
• high blood sugar (hyperglycaemia) - if your blood sugar is high, follow the instructions in section 4 'High blood sugar (hyperglycaemia)'.
• Make sure that 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 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 acute inflammation of the pancreas (acute pancreatitis).
- dehydration (loss of fluids from the body) can happen if you feel nauseous or vomit or if you have diarrhoea - it is important to drink plenty of fluids to prevent dehydration.

Skin changes at the injection site

Switch injection site 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 optimally if you inject into a lumpy, shrunken or thickened area (see section 3 'How to use this medicine'). Tell your doctor if you notice any skin changes at the injection site. Tell your doctor if you are currently injecting into these affected skin 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 dose 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

If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

Some medicines affect your blood sugar level - this may mean your Xultophy dose will need to be changed. 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. These medicines may make it harder to recognize 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
- 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
- tablets called 'thiazides' - for high blood pressure or if your body is holding onto too much water.

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

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

Warfarin or other blood thinners - medicines used to prevent excessive 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 long it takes for your blood to clot (called INR test).

Using this medicine and alcohol consumption

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 are planning to have a baby. 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 operate 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
- if you find it hard to recognize low blood sugar

Important information about some of this medicine's ingredients

Xultophy contains less than 1 mmol sodium (23 mg) per dose, so this medicine is essentially 'sodium free'.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

Only your doctor will determine your dose and how you should take this medicine.

Do not exceed the recommended dose.

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 most suitable for you.
- If it is not possible to use Xultophy at the same time every day, you may use it at a different time of the day. Make sure to have a minimum of 8 hours between doses.
- You do not have to inject Xultophy with a meal.
- Always follow your doctor's instructions 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 use this medicine

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 one 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' further down 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 possible overdose.

Detailed instructions for use appear later in this leaflet.

Do not use this medicine:

- if the pen is damaged or has not been stored correctly (see section 5).
- if the liquid you can see through the pen window is not clear and colourless.

Use in elderly patients (65 years old or over)

Xultophy can be used in elderly patients. 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 have accidentally taken a higher dose

If you use more Xultophy than you should, your blood sugar may get low (hypoglycaemia) or you may get nauseous or vomit. If your blood sugar gets low, follow the instructions in section 4 'Low blood sugar (hypoglycaemia)'.

If a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

If you forget a dose, inject the missed dose when you discover the mistake, and make sure there is a minimum of 8 hours between doses. If you discover that you

missed your previous dose when it is time to take your next dose, do not inject a double dose.

Adhere to the treatment as recommended by your doctor, even if your health improves.

If you stop taking this medicine

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 instructions in section 4 'High blood sugar (hyperglycaemia)'.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects

Like with all medicines, using Xultophy may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

The following serious side effects may happen with this medicine:

- Low blood sugar (very common: may affect more than 1 in 10 users):
If your blood sugar level gets low, you may pass out. Serious hypoglycaemia may cause brain damage and may be life-threatening. If you have signs of low blood sugar, take action to increase your blood sugar level straight away. See instructions in 'Low blood sugar (hypoglycaemia)' further down in this section.
- Serious allergic reaction (anaphylactic reaction) (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 following are signs of a serious allergic reaction:

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

Skin changes at the injection site:

If you inject insulin in the same place, the fatty tissue may shrink (lipoatrophy) or thicken (lipohypertrophy) (may affect up to 1 in 100 users). 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 optimally if you inject into a lumpy, shrunken or thickened area. Change the injection site with each injection to help prevent these skin changes.

Additional side effects:

Common side effects (may affect up to 1 in 10 users):

lower appetite, nausea or vomiting, diarrhoea, constipation, indigestion (dyspepsia), inflamed lining of the stomach (gastritis), stomach ache, heartburn or bloating - these effects 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 reactions usually go away after a few days. Contact your doctor if they do not disappear after a few weeks. Stop using Xultophy and see a doctor straight away if the reactions get worse.

- increase in pancreatic enzymes, such as lipase and amylase.

Uncommon side effects (may affect up to 1 in 100 users):

- 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 prevent dehydration.
- belching (eructation) and wind (flatulence).
- rash.
- itching.
- increased heart rate.
- Gallstones.
- inflamed gallbladder.
- changes in sense of taste.

Side effects of unknown frequency (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.

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, nausea, feeling very hungry, shaking, feeling nervous or worried, feeling 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, a biscuit 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 until 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 administer 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 received glucagon
- you have had low blood sugar a few times recently.

This is because the dosing of your Xultophy injections, or your 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
- do not use 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, 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 condition 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.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects:

You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page

(www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the injection pen label and on the package. The expiry date refers to the last day of that month.

Storage conditions

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. Discard the product 21 days after first opening.

Always keep the cap on the pre-filled injection 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.

6. Additional information

In addition to the active ingredients, this medicine also contains: glycerol, phenol, zinc acetate, hydrochloric acid and sodium hydroxide (for pH adjustment), water for injections.

What the medicine looks like and contents of the pack:

Xultophy is a clear and colourless solution.

Each unused pre-filled pen (3 mL) contains 300 units of insulin degludec and 10.8 mg liraglutide.

Available pack sizes are 1, 3, and 5 pens that contain 3 mL. Not all pack sizes may be marketed.

Registration holder's name and address: Novo Nordisk Ltd., 1 Atir Yeda Street, Kfar-Saba, 4464301.

Manufacturer's name and address: Novo Nordisk A/S, Novo Allé, DK-2880 Bagsværd, Denmark.

This leaflet was revised in August 2023 according to Ministry of Health guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry: 155-72-34607

Xultophy IL PIL AUG 2023 – Notification

Now turn over for information on how to use your pre-filled pen.

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 if you have not received 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 has been 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 enables administration of doses from:

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

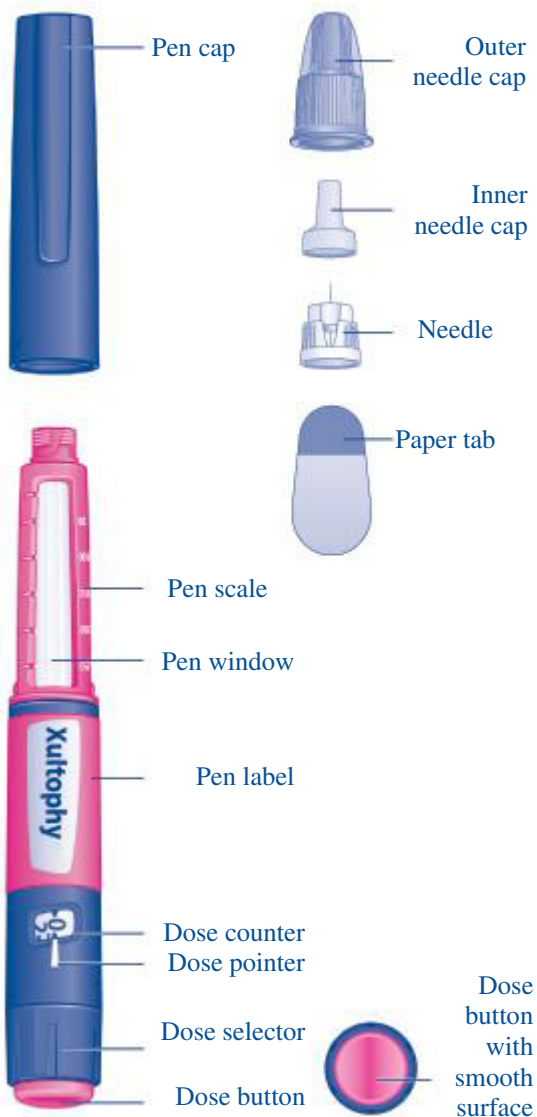
Your pen enables administration of doses in increments of 1 dose step. Do not do any conversion of your dose. The dose steps selected are the same as the number shown in the dose counter.

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

Important information

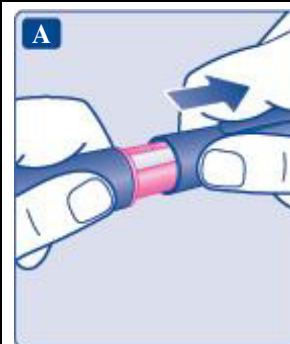
Pay special attention to these notes as they are important for safe use of the pen.

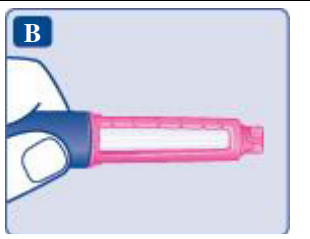

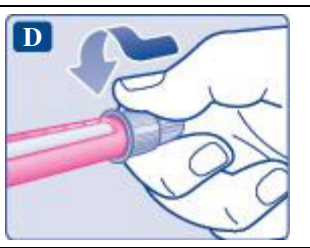
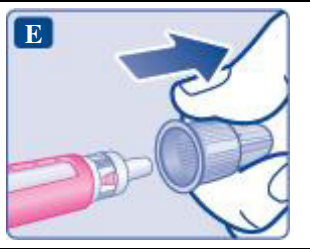


Pre-filled Xultophy® pen and needle
(example)



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"> • 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. 	
<ul style="list-style-type: none"> • Take a new needle, and tear off the paper tab. 	
<ul style="list-style-type: none"> • Push the needle straight onto the pen. Turn until it is on tight. 	
<ul style="list-style-type: none"> • 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. 	
<ul style="list-style-type: none"> • 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. <p>⚠ Always use a new needle for each injection. This may prevent blocked needles, contamination, infection and injection of an inaccurate dosage.</p> <p>⚠ Never use a bent or damaged needle.</p>	
<p>2 Check the flow</p> <ul style="list-style-type: none"> • 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 dose pointer must point to 0.
A drop of solution should appear at the needle tip.

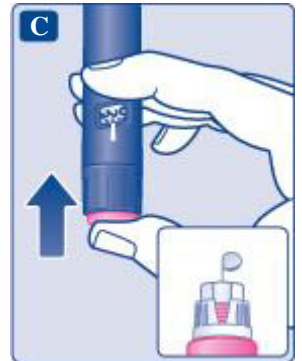
A small drop may remain at the needle tip, but it will not be injected.

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 step 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



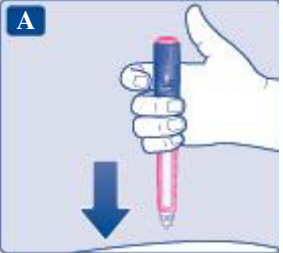
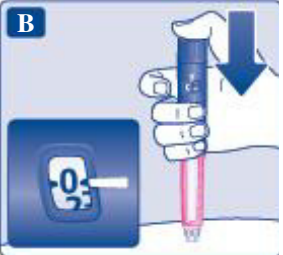

- **Turn the dose selector to select the dose you need.**
The dose counter shows the dose in dose steps.
If you select a wrong dose, you can turn the dose selector forward or backward to the correct dose.
The pen can dial up to a maximum of 50 dose steps.
The dose selector changes the number of dose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

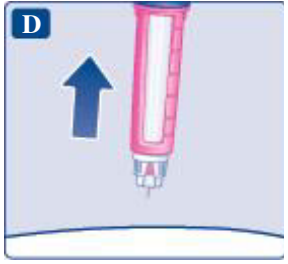
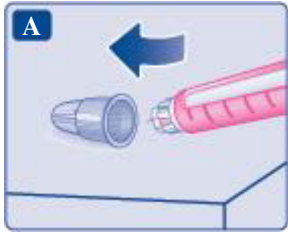
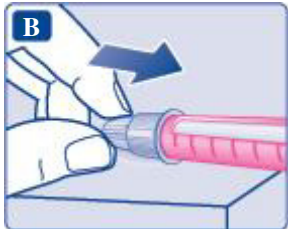
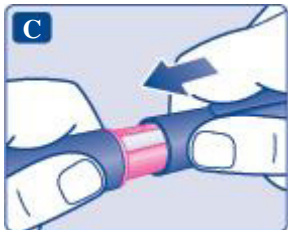
⚠ Always use the dose counter and the dose pointer to see how many dose steps you have selected before injecting the medicine.

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.



<p>How much solution is left?</p> <ul style="list-style-type: none"> • The pen scale only shows approximately how much solution is left in your pen. 	<p>A</p>  <p>Approx. how much solution is left</p>
<ul style="list-style-type: none"> • 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. <p>⚠ Be very careful to calculate correctly if splitting your dose. If you are in any doubt, inject the full dose with a new pen. If you split the dose incorrectly, you will inject too little or too much medicine. This may make your blood sugar level high or low.</p>	<p>B</p>  <p>Example Dose counter stopped: 42 dose steps left</p>
<p>4 Inject your dose</p> <ul style="list-style-type: none"> • 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 can interrupt the injection. 	<p>A</p> 
<ul style="list-style-type: none"> • Press and hold down the dose button until the dose counter shows 0. The dose pointer must point to 0. You may then hear or feel a click. 	<p>B</p> 
<ul style="list-style-type: none"> • 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 this is the case, the full dose will not be delivered, and you should increase the frequency of checking your blood sugar level. 	<p>C Count slowly: 1-2-3-4-5-6</p> 

<ul style="list-style-type: none"> • Remove the needle from your skin. If blood appears at the injection site, press lightly. Do not rub the area. <p>You may see a drop of solution at the needle tip after injecting. This is normal and does not affect your dose.</p> <p>! Always watch the dose counter to know how many dose steps you inject. Press and hold down the dose button 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>How to identify a blocked or damaged needle?</p> <ul style="list-style-type: none"> • 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. <p>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.</p>	
<p>5 After your injection</p> <ul style="list-style-type: none"> • Lead the needle tip into the outer needle cap on a flat surface without touching the needle or the outer cap. 	
<ul style="list-style-type: none"> • 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. 	
<ul style="list-style-type: none"> • Put the pen cap back on your pen after each use to protect the solution from light. <p>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.</p> <p>! Never try to put the inner needle cap back on the needle. You may stick yourself with the needle.</p>	

<p>⚠ Always remove the needle from your pen after each injection. This may prevent blocked needles, contamination, infection, leakage of solution and inaccurate dosing.</p>	
<p>⚠ Further important information</p> <ul style="list-style-type: none"> • 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. 	
<p>Caring for your pen</p> <ul style="list-style-type: none"> • 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 your pen is empty, it must be disposed of. • Do not try to repair your pen or pull it apart. 	