

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

This medicine is dispensed with a physician's prescription only

**LYUMJEV 100 units/ml
KWIKPEN
Solution for injection in a pre-filled pen**

Active ingredient and its quantity:

Each pen contains:

insulin lispro 100 units/ml (zinc crystals)

Each KwikPen delivers 1 to 60 units in steps of 1 unit.

Inactive ingredients and allergens in the preparation: see section 2 "Important information about some of the ingredients of this medicine" and section 6 "Additional Information".

Read this patient leaflet carefully in its entirety before using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, contact your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Lyumjev 100 units/ml KwikPen is used for the treatment of diabetes mellitus in adults, adolescents and children aged 1 year and above.

Therapeutic group: drugs used in diabetes, insulins and analogues for injection, fast-acting.

Lyumjev 100 units/ml KwikPen solution for injection in a pre-filled pen contains the active ingredient insulin lispro. It is a mealtime insulin that works more quickly than other medicines containing insulin lispro. Lyumjev contains ingredients that speed up absorption of insulin lispro into the body.

Diabetes is a condition in which your body does not make enough insulin or does not use insulin effectively, which results in effects such as high levels of sugar in the blood. Lyumjev is an insulin medicine that is used in the treatment of diabetes and so controls blood sugar. Effective treatment of diabetes, with good control of blood sugar, prevents long-term complications from your diabetes.

Treatment with Lyumjev helps to control blood sugar in the long term and prevent complications from your diabetes. Lyumjev has its maximum effect 1 to 3 hours after injection and the effect lasts for up to 5 hours. You should use Lyumjev 0-2 minutes before the start of the meal. In exceptional cases, Lyumjev can be injected up to 20 minutes after starting the meal.

Your doctor may tell you to use Lyumjev as well as a longer- or intermediate-acting insulin. Do not change your insulin unless your doctor tells you to.

The Lyumjev 100 units/ml KwikPen is a disposable pre-filled pen containing 3 ml (300 units, 100 units/ml) of insulin lispro. One KwikPen contains multiple doses of insulin. The KwikPen dials 1 unit at a time. **The number of units are displayed in the dose window, always check this before your injection.** You can give from 1 to 60 units in a single injection. **If your dose is more than 60 units, you will need to give yourself more than one injection.**

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

- you are sensitive (**allergic**) to the active ingredient (insulin lispro) or any of the other ingredients of this medicine (listed in section 6).
- you think your blood sugar is dropping (**hypoglycemia**). Further on, this leaflet tells you how to deal with low blood sugar (see section 3 under “If you accidentally take a higher dose”).

Special warnings regarding the use of this medicine

Talk to your doctor, pharmacist or nurse before using Lyumjev.

If you cannot see very well, you will need help from someone who has been trained to give injections.

- **Low blood sugar** (hypoglycemia).

Low blood sugar can be serious and untreated hypoglycemia may even lead to death.

Lyumjev starts to lower blood sugar faster than some other mealtime insulins. If hypoglycemia occurs, you may experience it earlier after an injection of Lyumjev. If you often have hypoglycemia or have difficulty recognizing it, please discuss this with your doctor or nurse. If your blood sugar levels are well controlled by your current insulin therapy or after long duration of diabetes, you may not feel the warning symptoms when your blood sugar is falling too low. Warning signs are listed later in this leaflet. For symptoms see “Common problems of diabetes”.

You must think carefully about when to have your meals, how often to exercise and how much to do. You must also keep a close watch on your blood sugar levels by testing your blood sugar often. Making changes to the types of insulin you use may cause your blood sugar to rise or fall too much. It may be necessary to increase the frequency of blood sugar testing if you are at risk of low blood sugars. Your doctor may need to change the doses of your other diabetes medicines.

- **High blood sugar** (hyperglycemia).

Stopping or not taking enough insulin may lead to high blood sugar (hyperglycemia) and diabetic ketoacidosis, serious conditions that can even lead to death. For symptoms see “Common problems of diabetes”.

- If your insulin treatment is being combined with one of a class of diabetes medicines called thiazolidinediones or glitazones, such as pioglitazone, tell your doctor as soon as possible if you get signs of heart failure such as unusual shortness of breath or rapid increase in weight or localized swelling caused by fluid retention (oedema).
- If you have a serious allergic reaction to insulin or any of the ingredients in Lyumjev, stop using this medicine and contact emergency medical services straight away.
- Always check the pack and the label for the name and type of the insulin when you get it from your pharmacy. Make sure you get the Lyumjev that your doctor has told you to use.
- Keep the carton or keep a note of the batch number on the carton. If you have a side effect, you can then provide that number when you report the adverse side effect. See “Reporting of side effects”.
- Always use a new needle for each injection to prevent infections and blocked needles. If a needle is blocked replace it with a new needle.

- **Skin changes at the injection site.**

The injection site should be rotated to prevent skin changes such as lumps under the skin. The insulin may not work well if you inject into a lumpy area (See “How to use this medicine?”). Contact your doctor if you are currently injecting into a lumpy area before you start injecting into 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

This medicine is not intended for use in children below the age of 1 year.

Drug Interactions

If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, inform your doctor or pharmacist. Some medicines affect your blood sugar level - this may mean your insulin dose has to change.

Your blood sugar levels may fall (hypoglycemia) if you take:

- other medicines for diabetes (oral and injectable)
- sulphonamide antibiotics (for infections)
- acetylsalicylic acid (for pain and mild fever and to prevent blood clotting)
- some antidepressants (monoamine oxidase inhibitors (MAOIs) or selective serotonin reuptake inhibitors (SSRIs))
- some angiotensin converting enzyme (ACE) inhibitors (for example captopril, enalapril) (for some heart problems or high blood pressure)
- angiotensin II receptor blockers (for high blood pressure or heart problems)
- somatostatin analogues (such as octreotide, which are used to treat a rare condition involving too much growth hormone)

Your blood sugar levels may rise (hyperglycemia) if you take:

- danazol (for endometriosis)
- the contraceptive pill (birth control pills)
- thyroid hormone replacement therapy (for thyroid problems)
- human growth hormone (for growth hormone deficiency)
- diuretics (for high blood pressure or if you have a build-up of water in your body)
- sympathomimetic agents (for serious allergic reactions or used in some cold remedies)
- corticosteroids (to treat asthma or autoimmune conditions)

Beta-blockers (used for high blood pressure, arrhythmia or angina) make it harder to recognize the warning signs of low blood sugar.

Using this medicine and food

You should use Lyumjev 0-2 minutes before the start of the meal. In exceptional cases, Lyumjev can be injected up to 20 minutes after starting the meal.

Using this medicine and alcohol consumption

Your blood sugar levels may either rise or fall if you drink alcohol. Therefore the amount of insulin needed may change. You should therefore monitor your blood sugar level more often than usual.

Pregnancy and breastfeeding

There is no available data on the use of Lyumjev in pregnant women.

If you are planning to get pregnant, think you may be pregnant, are pregnant or breastfeeding, ask your doctor, nurse or pharmacist for advice before taking this medicine. The amount of insulin you need usually falls during the first 3 months of pregnancy and increases for the remaining 6 months. After you have had your baby your insulin requirements will likely return to how much you needed before your pregnancy .

There is no available data on the use of Lyumjev in breastfeeding women.

Driving and using machines

Your ability to concentrate and react may be reduced if you have hypoglycemia. Please keep this possible problem in mind in all situations where you might put yourself and others at risk (e.g. driving a car or using machines). You should contact your doctor about driving if you have:

- frequent episodes of hypoglycemia
- reduced or absent warning signs of hypoglycemia

Important information about some of the ingredients of this medicine

This medicine contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use this medicine according to your doctor's instructions. You must check with the doctor, pharmacist or nurse if you are not sure about the dosage and manner of treatment with this preparation. They will have told you exactly how much Lyumjev to use, when to use it, and how often. They will also tell you how often to visit your diabetes clinic .

The dosage and manner of treatment will be determined only by the doctor.

Do not exceed the recommended dose.

To prevent the possible transmission of disease, each pen must be used by you only, even if the needle is changed.

You should always have spare insulin and another injection device in case you need them.

If you are blind or visually impaired, you will need help from someone to make your injections.

Your doctor may tell you to use Lyumjev as well as a longer- or intermediate-acting insulin. Inject them separately. Lyumjev should not be mixed with any other insulin.

When to inject Lyumjev

Lyumjev is a mealtime insulin for subcutaneous injection and should be administered 0-2 minutes before the start of the meal. In exceptional cases, Lyumjev can be injected up to 20 minutes after starting the meal.

How much insulin to use

Your doctor will work out your dose based on your blood sugar and body weight and explain

- How much Lyumjev you need at each meal.
- How and when to check your blood sugar level .
- How to change your insulin dose depending on your blood sugar levels.
- What to do if you change your diet, or change how much you exercise, if you are ill or if you are using other medicines.
- If you change the type of insulin you use, you may have to take more or less than before. This might just be for the first injection or it may be a gradual change over several weeks or months.

Do not use Lyumjev

- If it does not look like water. Lyumjev must be clear, have no color and no solid pieces in it. Check each time you inject yourself.
- If Lyumjev has not been stored correctly (see section 5 "How to store the medicine?").
- If the pen is damaged in any way, do not use.

Getting the KwikPen ready to use (see instructions for use)

- First wash your hands.
- Read the instructions on how to use your pre-filled insulin pen. Please follow the instructions carefully. Here are some reminders.
- Use a new needle (needles are not included).
- Prime your KwikPen before each use. This checks that insulin comes out and clears the air bubbles from your KwikPen. There may still be some small air bubbles left in the pen. Small air bubbles are normal and will not affect your dose.
- The number of units are displayed in the dose window, always check this before your injection.

Injecting Lyumjev

- Before you make an injection, clean your skin.
- Inject under the skin (subcutaneous injection), as you were taught by your physician or nurse.
- After your injection, leave the needle in the skin for 5 seconds to make sure you receive the full dose. Make sure you inject at least 1 cm from the last injection and that you 'rotate' the places you inject (upper arm, thigh, buttocks or abdomen).
- If you do not have enough insulin in the pen to complete your dose, make a note of how much you still need to take. Prime a new pen and inject the remaining dose.
- If you need to inject another insulin at the same time as Lyumjev, use a different injection site.
- Do not inject directly into a vein.

After injecting

- As soon as you have done the injection, unscrew the needle from the KwikPen using the outer needle cap. This will keep the insulin sterile and stop it from leaking. It also stops air entering the pen and your needle from clogging. **Do not share your needles with another person. Do not share your pen with another person.** Replace the cap on your pen.
- If you are unsure how much you have injected then check your blood sugar levels before deciding if you need another injection.

Further injections

- Every time you use a KwikPen you must use a new needle. Before every injection, clear any air bubbles. You can see how much insulin is left by holding the KwikPen with the needle pointing up.
- Once the KwikPen is empty, do not use it again.

If you accidentally take a higher dose

If you inject too much Lyumjev, or are unsure how much you have injected, a low blood sugar may occur. Check your blood sugar.

If your blood sugar is low (hypoglycemia) and you can treat yourself, eat glucose tablets, sugar or drink a sugary drink. Then eat fruit, biscuits, or a sandwich, as your doctor or nurse has advised you and have some rest. This will often get you over a low blood sugar or a minor insulin overdose. Check your blood sugar again after 15-20 mins until blood sugar is stabilized.

If you are unable to treat yourself (severe hypoglycemia) because you feel too dizzy, weak, confused, have difficulty talking, lose consciousness or have a seizure you may need to be treated with glucagon. This can be given by someone who knows how to use it. Eat glucose or sugar after the glucagon. If glucagon does not work, you will have to go to the hospital or call emergency services. Ask your doctor to tell you about glucagon.

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

Let them know that if you pass out, they must: turn you on your side to avoid choking, get medical help straight away and not give you any food or drink because you may choke.

If you have taken an overdose or if a child has accidentally swallowed the medicine, contact a doctor or hospital Emergency Room immediately and bring the medicine pack with you.

If you forget to take the medicine

If you forget to use your insulin or you use less than you should, or are unsure how much you have injected, your blood sugar may get too high (hyperglycemia). Check your blood sugar level to decide if an insulin dose is needed. Resume your usual dosing schedule at your next meal.

If you stop taking the medicine

Do not stop or change your insulin unless your doctor tells you to. If you use less Lyumjev than you should, a high blood sugar may occur.

If high blood sugar (hyperglycemia) is not treated it can be very serious and cause headaches, nausea, vomiting, abdominal pain, dehydration, unconsciousness, coma or even death (see section 4).

Three simple steps to reduce your risk of hypoglycemia or hyperglycemia are:

- Always keep a spare pen in case you lose your KwikPen or it gets damaged.
- Always carry something to show you are diabetic.
- Always carry sugar with you.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine.

Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

Like all medicines, this medicine can cause side effects in some users. Do not be alarmed while reading the list of side effects. You may not experience any of them.

Low blood sugar (hypoglycemia) is very common with insulin treatment (may affect more than 1 in 10 users). It can be very serious. If your blood sugar level falls too much you may become unconscious. Serious hypoglycemia may cause brain damage and may be life-threatening. If you have symptoms of low blood sugar, act **immediately** to increase your blood sugar level. See section 3 under 'If you accidentally take a higher dose'.

Allergic reactions are common (may affect up to 1 in 10 users). They may be severe and they may include the following symptoms:

- rash over the whole body
- difficulty in breathing
- wheezing
- blood pressure dropping
- heart beating fast
- sweating

If you have a serious allergic reaction (including an anaphylactic attack) to insulin or any of the ingredients in Lyumjev, stop using this medicine and contact emergency medical services straight away.

Other side effects include:

Common Side Effects (may affect up to 1 in 10 users)

Injection site reactions. Some people get rash, redness, inflammation, pain, swelling, bruising or itching around the area of the insulin injection. This usually clears up in a few minutes to a few weeks without needing to stop Lyumjev. If you have injection site reactions, tell your doctor.

Uncommon Side Effects (may affect up to 1 in 100 users)

Skin changes at the injection site: If you inject insulin too often at the same place, the fatty tissue may either shrink (lipoatrophy) or thicken (lipohypertrophy). Lumps under the skin may also be caused by the build-up of a protein called amyloid (cutaneous amyloidosis). The insulin may not work very well if you inject into a lumpy area. Change the injection site with each injection to help prevent these skin changes.

Other potential side effects

Swelling in arms or ankles due to fluid retention (oedema) particularly at the start of insulin therapy or during a change in your diabetes medicines.

If a side effect appears, if any side effect gets worse, or if you suffer from a side effect not mentioned in the leaflet, you should consult the doctor.

Reporting of Side Effects

Side effects can be reported to the Ministry of Health by clicking on the link “Reporting Side Effects due to Drug Treatment” that can be found on the Home Page of the Ministry of Health’s website (www.health.gov.il), which refers to the online form for reporting side effects, or via the following link: <https://sideeffects.health.gov.il>

Common problems of diabetes

Low blood sugar

Low blood sugar (hypoglycemia) means there is not enough sugar in the blood. This can be caused if:

- you take too much Lyumjev or other insulin;
- you miss or delay meals or change your diet;
- you exercise or work too hard just before or after a meal;
- you have an infection or illness (especially diarrhoea or vomiting);
- there is a change in your need for insulin for example if you lose weight; or you have trouble with your kidneys or liver which gets worse.

See section “If you accidentally take a higher dose”.

The first symptoms of low blood sugar usually come on quickly and include the following:

- tiredness
- rapid heart beat
- nervousness or shakiness
- nausea (feeling sick)
- headache
- cold sweat

If you are not confident about recognizing your warning symptoms, avoid situations such as driving a car, in which you or others would be put at risk by hypoglycemia.

High blood sugar (hyperglycemia) and diabetic ketoacidosis

Hyperglycemia (too much sugar in the blood) means that the levels of glucose in your body are too high. Hyperglycemia can be brought about by:

- not taking your insulin;
- using less insulin than your body needs;
- an imbalance between the amount of carbohydrates you eat and the insulin you take; or
- fever, infection or emotional stress.

The early symptoms of hyperglycemia are:

- being very thirsty
- headache
- feeling sleepy
- urinating more often

Hyperglycemia can lead to diabetic ketoacidosis. The first symptoms come on slowly over many hours or days. Additional symptoms include the following:

- nausea and/or vomiting
- abdominal pain
- rapid pulse
- heavy breathing
- moderate or large amounts of urine ketones. Ketones are produced when your body burns fat for energy instead of glucose.

If you have any of these symptoms and high sugars **get medical help immediately**. See section 'If you forget to take the medicine'.

Illness

If you are ill, especially if you feel sick (nauseous) or are sick (vomiting), the amount of insulin you need may change. **Even when you are not eating normally, you still need insulin.** Test your urine or blood, follow your 'sick rules', and tell your doctor.

5. HOW TO STORE THE MEDICINE?

Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.

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

Storage conditions

Before first use

Store in a refrigerator (2°C to 8°C).

Do not freeze.

Keep in the outer carton in order to protect from light.

After first use

Do not store above 30°C.

Do not freeze.

Do not refrigerate.

The KwikPen should not be stored with the needle attached. Keep the cap on the pen in order to protect from light.

Discard after 28 days **even if some of the solution remains**.

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 to protect the environment.

6. ADDITIONAL INFORMATION

In addition to the active ingredient, the medicine also contains:

glycerol, sodium citrate dihydrate, metacresol, magnesium chloride hexahydrate, zinc oxide, treprostinil sodium, hydrochloric acid and sodium hydroxide (for PH adjustment), water for injections.

What does the medicine look like and what are the contents of the pack:

Lyumjev 100 units/ml KwikPen solution for injection is a clear, colorless, aqueous solution in a pre-filled pen. Each pre-filled pen contains 300 units (3 milliliters).

Pack sizes of 1, 2 or 5 pre-filled pens.

Not all pack sizes may be marketed.

The Lyumjev 100 units/ml KwikPen is taupe. The dose knob is blue with raised ridges on side. The label is blue and white. Each Lyumjev 100 units/ml KwikPen delivers 1 to 60 units in steps of 1 unit.

Registration holder name and address:

Eli Lilly Israel Ltd., 4 HaSheizaf st., POB 4246 Ra'anana 4366411

Manufacturer name and address:

Eli Lilly & Company, Indianapolis, Indiana, USA

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Revised in December 2023 according to MOHs guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
169-13-36423-00

Instructions for Use

Lyumjev 100 units/ml KwikPen solution for injection in a pre-filled pen insulin lispro (zinc crystals)



PLEASE READ THESE INSTRUCTIONS BEFORE USE

Read the instructions for use before you start taking Lyumjev and each time you get another Lyumjev 100 units/ml KwikPen. There may be new information. This information does not take the place of talking to your healthcare professional about your medical condition or your treatment.

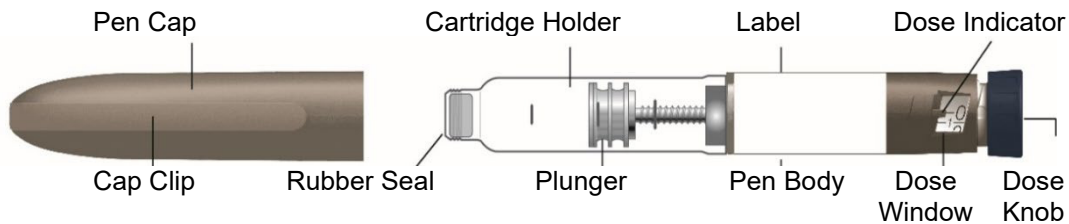
Do not share your Lyumjev 100 units/ml KwikPen with other people, even if the needle has been changed. Do not reuse or share needles with other people. You may give other people a serious infection or get a serious infection from them.

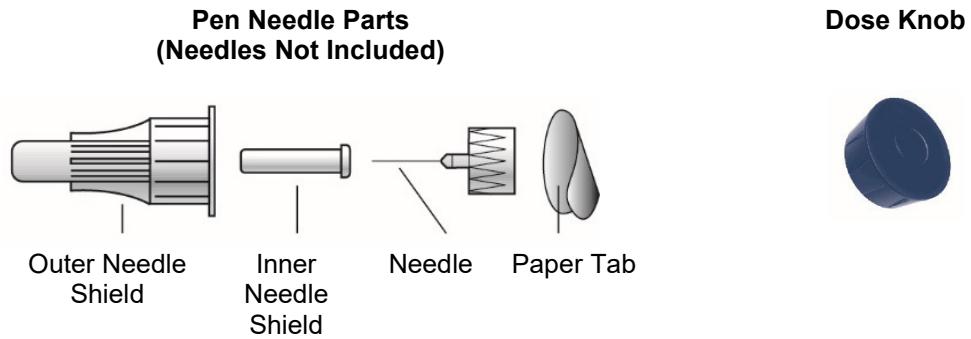
Lyumjev 100 units/ml KwikPen (“Pen”) is a disposable pre-filled pen containing 3 ml (300 units, 100 units/ml) of insulin lispro solution for injection.

- Your healthcare professional will tell you how many units to give as your dose and how to inject your prescribed dose of insulin.
- You can give yourself more than 1 dose from the Pen.
- Each turn of the dose knob dials 1 unit of insulin. You can give from 1 to 60 units in a single injection.
- If your dose is more than 60 units, you will need to give yourself more than 1 injection. Always check the number in the dose window to make sure you dialed the correct dose.
- The plunger only moves a little with each injection, and you may not notice that it moves. The plunger will only reach the end of the cartridge when you have used all 300 units in the Pen.

People who are blind or have vision problems should not use the Pen without help from a person trained to use the Pen.

Lyumjev 100 units/ml KwikPen Parts





How to recognize your Lyumjev 100 units/ml KwikPen

- Pen color: Taupe
- Dose Knob: Blue, with raised ridges on side
- Label: Blue and white

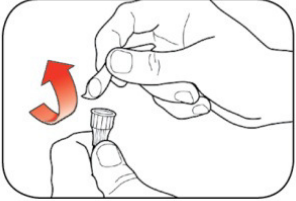
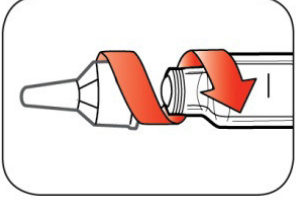
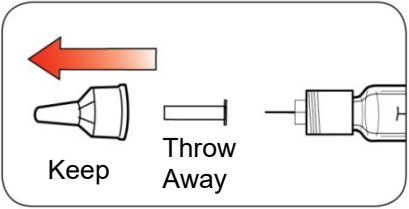
Supplies needed to give your injection

- Lyumjev 100 units/ml KwikPen
- KwikPen compatible needle (BD [Becton, Dickinson and Company] Pen needles recommended)
- Swab or gauze

Preparing your Pen

- Wash your hands with soap and water.
- Check the Pen to make sure you are taking the right type of insulin. This is especially important if you use more than 1 type of insulin.
- **Do not** use your Pen past the expiry date printed on the label or for more than 28 days after you first start using the Pen.
- Always use a **new needle** for each injection to help prevent infections and blocked needles.

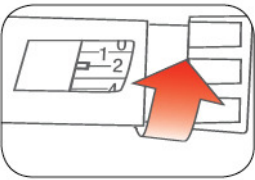


<p>Step 1:</p> <ul style="list-style-type: none"> • Pull the Pen cap straight off. - Do not remove the Pen label. • Wipe the rubber seal with a swab. 	
<p>Step 2:</p> <ul style="list-style-type: none"> • Check the liquid in the Pen. • Lyumjev should look clear and colorless. Do not use if it is cloudy, colored, or has particles or clumps in it. 	

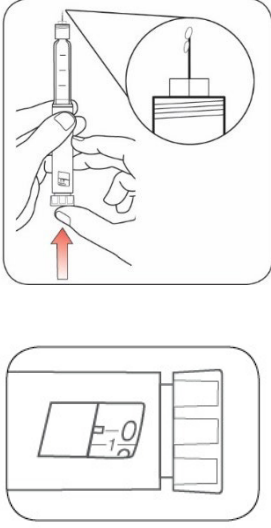
<p>Step 3:</p> <ul style="list-style-type: none"> • Select a new needle. • Pull off the paper tab from the outer needle shield. 	
<p>Step 4:</p> <ul style="list-style-type: none"> • Push the capped needle straight onto the Pen and twist the needle on until it is tight. 	
<p>Step 5:</p> <ul style="list-style-type: none"> • Pull off the outer needle shield. Do not throw it away. • Pull off the inner needle shield and throw it away. 	

Priming your Pen

Prime before each injection.

- Priming your Pen means removing the air from the needle and cartridge that may collect during normal use and ensures that your Pen is working correctly.
- If you **do not** prime before each injection, you may get too much or too little insulin.

<p>Step 6:</p> <ul style="list-style-type: none"> • To prime your Pen, turn the dose knob to select 2 units. 	
<p>Step 7:</p> <ul style="list-style-type: none"> • Hold your Pen with the needle pointing up. Tap the cartridge holder gently to collect air bubbles at the top. 	
<p>Step 8:</p> <ul style="list-style-type: none"> • Continue holding your Pen with the needle pointing up. Push the dose knob in until it stops and "0" is seen in the dose window. Hold the dose knob in and count to 5 slowly. 	

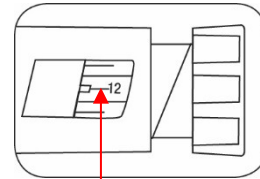
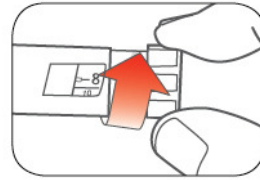
<p>You should see insulin at the tip of the needle.</p> <ul style="list-style-type: none">- If you do not see insulin, repeat priming steps 6 to 8, but not more than 4 times.- If you still do not see insulin, change the needle and repeat priming steps 6 to 8. <p>Small air bubbles are normal and will not affect your dose.</p>	
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Selecting your dose

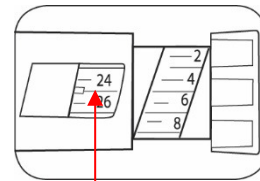
- You can give from 1 to 60 units in a single injection.
- If your dose is more than 60 units, you will need to give more than 1 injection.
 - If you need help with dividing up your dose the right way, ask your healthcare professional.
 - Use a new needle for each injection and repeat the priming steps.

Step 9:

- Turn the dose knob to select the number of units you need to inject. The dose indicator should line up with your dose.
 - The Pen dials 1 unit at a time.
 - The dose knob clicks as you turn it.
 - **Do not** dial your dose by counting the clicks. You may dial the wrong dose. This may lead to getting too much insulin or not enough insulin.
 - The dose can be corrected by turning the dose knob in either direction until the correct dose lines up with the dose indicator.
 - The **even** numbers are printed on the dial. The example to the right shows 12 units.
 - The **odd** numbers, after the number 1, are shown as full lines between the numbers. The example to the right shows 25 units.
- **Always check the number in the dose window to make sure you have dialed the correct dose.**



Example: 12 units shown in the dose window



Example: 25 units shown in the dose window

- The Pen will not let you dial more than the number of units left in the Pen.
- If you need to inject more than the number of units left in the Pen, you may either:
 - inject the amount left in your Pen and then use a new Pen to give the rest of your dose,

or

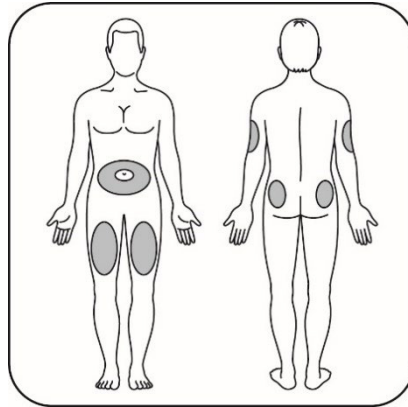
 - get a new Pen and inject the full dose.
- It is normal to see a small amount of insulin left in the Pen that you cannot inject.

Giving your injection

- Inject your insulin as your healthcare professional has shown you.
- Change (rotate) your injection site for each injection.
- **Do not** try to change your dose while injecting.

Step 10:

- Choose your injection site.
Lyumjev is injected under the skin (subcutaneously) of your stomach area, buttocks, upper legs or upper arms.
- Wipe your skin with a swab, and let your skin dry before you inject your dose.

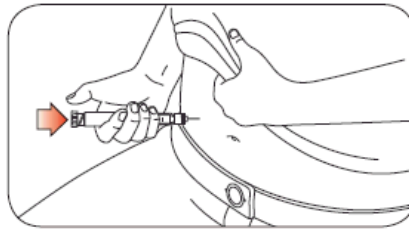


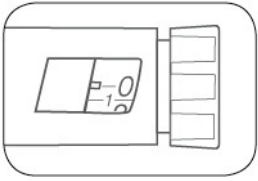
Step 11:

- Insert the needle into your skin.
- Push the dose knob all the way in.
- Continue to hold the dose knob in and **slowly count to 5** before removing the needle.

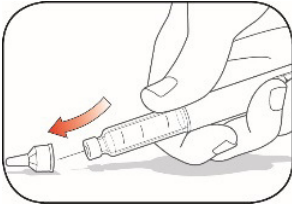
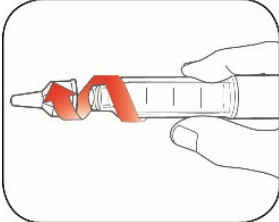
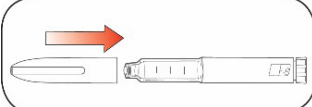


Do not try to inject your insulin by turning the dose knob. You will **not** receive your insulin by turning the dose knob.



<p>Step 12:</p> <ul style="list-style-type: none"> • Pull the needle out of your skin. <ul style="list-style-type: none"> - A drop of insulin at the needle tip is normal. It will not affect your dose. • Check the number in the dose window. <ul style="list-style-type: none"> - If you see “0” in the dose window, you have received the full amount you dialed. - If you do not see “0” in the dose window, you did not receive your full dose. Do not redial. Insert the needle into your skin and finish your injection. - If you still do not think you received the full amount you dialed for your injection, do not start over or repeat that injection. Monitor your blood glucose as instructed by your healthcare professional. - If you normally need to give 2 injections for your full dose, be sure to give your second injection. <p>The plunger only moves a little with each injection, and you may not notice that it moves.</p> <p>If you see blood after you take the needle out of your skin, press the injection site lightly with a piece of gauze or a swab. Do not rub the area.</p>	
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After your injection

<p>Step 13:</p> <ul style="list-style-type: none"> • Carefully replace the outer needle shield. 	
<p>Step 14:</p> <ul style="list-style-type: none"> • Unscrew the capped needle and dispose of it as described below (see “Disposing of Pens and needles” section). • Do not store the Pen with the needle attached to prevent leaking, blocking the needle, and air from entering the Pen. 	
<p>Step 15:</p> <ul style="list-style-type: none"> • Replace the Pen cap by lining up the cap clip with the dose indicator and pushing straight on. 	

Disposing of Pens and needles

- Put used needles in a sharps container or a hard plastic container with a secure lid. **Do not** throw needles directly into your household waste.
- **Do not** recycle the filled sharps container.
- Ask your healthcare professional about options to dispose of the Pen and the sharps container properly.
- The directions regarding needle handling are not intended to replace local, healthcare professional or institutional policies.

Troubleshooting

- If you cannot remove the Pen cap, gently twist the cap back and forth, and then pull the cap straight off.
- If the dose knob is hard to push:
 - pushing the dose knob more slowly will make it easier to inject.
 - your needle may be blocked. Put on a new needle and prime the Pen.
 - you may have dust, food, or liquid inside the Pen. Throw the Pen away and get a new Pen.

If you have any questions or problems with your Lyumjev 100 units/ml KwikPen, call your healthcare professional for help or contact your local Lilly affiliate.