

Your doctor has prescribed Adlyxin™ (lixisenatide) injection. This medicine comes in a self-injectable pre-filled pen. In this video, we will demonstrate how to use and store your pre-filled Adlyxin pen. Before we get started, let's review the indication for your Adlyxin pre-filled pen.

### **What is Adlyxin (lixisenatide) injection?**

Adlyxin is an injectable prescription medicine that may improve blood sugar (glucose) control in adults with type 2 diabetes, when used with diet and exercise.

- Adlyxin is not insulin and is not a substitute for insulin.
- Adlyxin is not for people with type 1 diabetes or people with diabetic ketoacidosis.
- Adlyxin has not been studied in people with a history of pancreatitis.
- Adlyxin has not been studied in people who use short-acting insulin.
- It is not known if Adlyxin is safe and effective in children.
- Adlyxin has not been studied in, and is not for, people who have a stomach problem that causes slow emptying of the stomach (gastroparesis).

Your Adlyxin pen comes with printed instructions. After you watch this video, **be sure to read these instructions before using your pen.**

Remember, **do not share your Adlyxin pen with other people, even if the needle has been changed. Sharing pens can spread serious infections.**

Using your Adlyxin pen, you will inject **1 dose per day**, under the skin, also called subcutaneous injection. Before using the pen, **talk with your healthcare professional about how to use it to inject.** Be sure to ask for help if you have any problems handling the pen, for example, if you have problems with your eyesight.

Adlyxin comes in two different strengths, each in a different color pre-filled pen for injection.

- **The green pen contains 14 pre-set doses of 10 micrograms of Adlyxin.**
- **The burgundy pen contains 14 pre-set doses of 20 micrograms of Adlyxin.**

Although each pen delivers a different daily dose, they are used in the same way. You **MUST** start your treatment with the green 10-microgram Adlyxin pen, taking 1 dose per day for 14 days before starting treatment with the burgundy 20-microgram pen on Day 15.

**Throw away the used Adlyxin pen after 14 days, even if there is some medicine left in the pen.**

Now let's take a closer look at your Adlyxin pen. Each pen has a pen cap, a rubber seal where you will attach a needle, and an Adlyxin container with a dose scale. The pen also has an activation window that indicates when the pen is ready to use, an arrow window, and an injection button.

Inside the Adlyxin container, you'll see a black plunger. With each injection, this black plunger will move along the markings on the dose scale to show you how many doses are left in your pen.

Before you use the Adlyxin pen, make sure you are using the correct color pen and that it has not passed its expiration date. The expiration date can be found on the back of the pen's label as well as on the box.

Do not change your dose unless your healthcare provider has told you to change your dose.

Check the label on the pen each time you give your Adlyxin injection to make sure you are using the correct medication.

Inject Adlyxin only by using this pen with approved needles. Never use another syringe to withdraw medication from the pen.

You will need to use a new needle for each new injection. This helps prevent contamination of Adlyxin or possible needle blockage.

Only use needles that have been approved for use with the Adlyxin pen. These include needles from Becton Dickinson, Ypsomed, and Owen Mumford that are 8 millimeters long or shorter. Ask your healthcare professional which needle is best for you.

Do not reuse needles or share needles with another person.

Now let's activate a pen for self-injection.

**You start treatment with the green 10-microgram Adlyxin pen**, taking 1 dose a day within 1 hour before the first meal of the day, and at the same meal each day, for 14 days. So to begin, we **will activate the green Adlyxin pen**. Remember, you will activate your green pen on the same day as your first injection.

**Do not activate the burgundy 20-microgram pen until you have finished all 14 doses of the green pen.** You will activate and inject your burgundy pen on Day 15.

On one end of the Adlyxin pen, you'll see an activation window. If the pen has not been activated, the activation window will appear orange. If the pen has already been activated, the window will be white. Once the pen is activated, **do not activate it again**. An activated pen must be discarded after 14 days, even if there is some medicine left in the container.

Activation is a five-step process.

First, make sure your hands are clean, and then pull off the pen cap. Check the appearance of the liquid in the Adlyxin container. It should be clear and colorless, with no particles.

If the liquid is cloudy or contains particles, do not use the pen and contact your healthcare professional.

Tiny air bubbles in the container are normal. Also check that the activation window is orange.

Now we'll attach a needle to the pen. Please note that each needle has a protective seal, an outer needle cap, and an inner needle cap.

Take the **new needle** and remove the protective seal from the outer needle cap.

Line up the needle in the outer cap with the pen. Keep the pen and needle straight as you push the needle into the pen, then screw the needle clockwise until it is secure.

After you have attached the needle to the pen, **pull off**, but do not unscrew, the outer needle cap and set it aside. You'll need it later to remove the needle from the pen.

Next, remove the inner needle cap and throw it away. Now that the needle is exposed, take care not to injure yourself.

**Pull the injection button out firmly until it stops.**

Check the arrow window, the black arrow should now be pointing towards the needle and not the injection button.

Point the needle into a container, for example a paper cup.

**Firmly press the injection button all the way in.** You will feel or hear a “click.” After the “click,” keep the injection button pressed in and slowly count to 2.

When liquid comes out of the needle tip, you know that the pen is working correctly. If no liquid comes out of the pen, the needle may be blocked or not properly attached to the pen.

If this happens, simply remove the needle from the pen, attach a new needle, and repeat the activation process.

If no liquid comes out after replacing the needle, your Adlyxin pen may be damaged. Do not use this Adlyxin pen and contact your healthcare professional for help.

Never use another syringe to withdraw medication from the pen.

Now let's make sure that pen activation is complete.

Check that the activation window is now white and that the arrow is pointing back to the injection button. The black plunger should have moved down to the dotted line on the Adlyxin container.

The Adlyxin pen is now activated and ready to use. It will **not need to be activated again**.

After your pen has been activated, it must be discarded after 14 days, even if there is some medicine left. Remember to keep track of your activation date and your daily injections.

Now that your Adlyxin pen has been successfully activated, let's go through the seven steps required for daily injection.

Always perform a Pen Check before each injection. **Check the label** to make sure you are using the correct pen and that the pen has not passed the expiration date. **Check that the activation window is white.** Remove the pen cap and **check that the liquid** in the Adlyxin container is clear and colorless with no particles. Finally, **check the number of doses remaining in the pen** by looking at where the black plunger is on the dose scale.

Always use a new needle for each injection. However, if you inject your **first dose immediately** after activation, you will **not** need to replace the needle.

For all your remaining injections, you'll need to attach a **new needle** to your pen.

Just as we described in the “activation” section, remove the protective seal from the outer needle cap, line up the needle with the pen, push the needle onto the pen, then screw the needle on until it is secure. Pull off the outer needle cap and set it aside, and then remove the inner needle cap and throw it away. Again, remember to be careful not to injure yourself with the exposed needle.

Once the needle is securely in place, pull out the injection button firmly until it stops.

The black arrow on your pen will now be pointing towards the needle instead of the injection button.

Next, choose the area on your body where you will inject. Adlyxin must be injected under the skin in any of the areas highlighted in blue here. These areas include the thigh, abdomen, and upper arm.

Make sure to rotate injection sites within the area you have selected, and choose a new site each time you inject a dose. **DO NOT** use the same spot for every injection.

Once you've chosen an injection site, grasp a fold of skin at the site and insert the needle. **Press the injection button all the way in. You will feel or hear a "click."**

**Keep the injection button pressed in and hold for 2 seconds before removing the needle. If you don't hold the injection button in, or if you remove the needle too early, you may not get the full dose of Adlyxin.**

Once you've completed your injection, **remove the needle by gripping the widest part of the outer needle cap and guiding the needle into the outer needle cap.** Be careful, the needle can puncture the cap if it is recapped at an angle.

**Next, grip and squeeze the widest part of the outer needle cap while turning the pen several times with your other hand to unscrew the needle from the pen.**

When the needle has been removed, replace the pen cap.

Immediately throw away the needle in an FDA-cleared sharps disposal container. Do not throw the needle away in your household trash. For more information on containers, visit [www.fda.gov/safesharpsdisposal](http://www.fda.gov/safesharpsdisposal).

For each new injection, you will repeat steps 1 through 6—injecting 1 dose each day within 1 hour before the first meal of the day, and at the same time each day, for the next 14 days.

Each pen has 14 doses of Adlyxin. The Adlyxin pen will be empty when the black plunger has moved all the way down to the zero marker on the dose scale and the injection button can no longer be fully pulled out.

When you have finished all 14 daily doses from the green 10-microgram Adlyxin pen, continue treatment the next day with the burgundy 20-microgram Adlyxin pen.

The burgundy Adlyxin pen is used in exactly the same way as the green Adlyxin pen.

Remember to activate the burgundy pen before injecting the first dose.

Now let's review how to store and dispose of your Adlyxin pens.

- Keep your Adlyxin pens in a safe place—specifically out of the reach, and sight, of children.
- Protect your pens from light by replacing the cap after use.
- And remember to store your pens in a clean area where they will be protected from dust and dirt.
- Store your pens that have **not been activated** in the refrigerator. The temperature should be set between 36 and 46 degrees Fahrenheit, or 2 and 8 degrees Celsius.
- Do not freeze your pens and do not use a pen that has been frozen.

- Before you activate a pen, allow it to adjust to room temperature.
- Once an Adlyxin pen has been activated, store it at room temperature—no higher than 86 degrees Fahrenheit or 30 degrees Celsius.
- Never store your pen with a needle attached.
- Always handle your Adlyxin pen with care.
- Clean the outside of your Adlyxin pen by wiping it with a damp cloth. Never soak or wash your Adlyxin pen as this may damage it.
- If, for any reason you think your Adlyxin pen may be damaged, do not try to repair it or use it.
- It is time to throw your Adlyxin pen away when it is empty, or when it is 14 days past the activation date, or when the pen has expired as noted by the expiration date.
- Make sure the cap is on the pen for proper disposal.
- Throw out your Adlyxin pens in an FDA-cleared sharps disposal container, not in your household trash.
- For detailed information on proper disposal in your state, visit [www.fda.gov/safesharpsdisposal](http://www.fda.gov/safesharpsdisposal).

Now let's review the:

## Indication and Full Important Safety Information for Adlyxin

### What is Adlyxin (lixisenatide) injection?

Adlyxin is an injectable prescription medicine that may improve blood sugar (glucose) control in adults with type 2 diabetes, when used with diet and exercise.

- Adlyxin is not insulin and is not a substitute for insulin.
- Adlyxin is not for people with type 1 diabetes or people with diabetic ketoacidosis.
- Adlyxin has not been studied in people with a history of pancreatitis.
- Adlyxin has not been studied in people who use short-acting insulin.
- It is not known if Adlyxin is safe and effective in children.
- Adlyxin has not been studied in, and is not for, people who have a stomach problem that causes slow emptying of the stomach (gastroparesis).

## Important Safety Information for Adlyxin (lixisenatide) Injection

### What is the most important information I should know about Adlyxin?

**Do not share your Adlyxin pen with other people, even if the needle has been changed. You may give other people a serious infection, or get a serious infection from them.**

### Adlyxin can cause serious side effects, including:

- **inflammation of the pancreas (pancreatitis)**, which may be severe and lead to death. Stop using Adlyxin and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel pain from your abdomen to your back.

### Do not use Adlyxin if you:

- are allergic to lixisenatide or any of the other ingredients in Adlyxin.

Symptoms of severe allergic reaction with Adlyxin may include swelling of your face, lips, tongue, or throat, problems breathing or swallowing, severe rash or itching, fainting or feeling dizzy, and very rapid heartbeat.

**Before using Adlyxin, tell your healthcare provider if you:**

- have or have had pancreatitis, stones in your gallbladder, or a history of alcoholism.
- have or have had kidney problems.
- have severe problems with your stomach, such as delayed emptying of your stomach (gastroparesis) or problems with digesting food.
- are pregnant or breastfeeding or plan to become pregnant or breastfeed. It is not known if Adlyxin will harm your unborn baby or if Adlyxin passes into your breastmilk.

Tell your healthcare provider about all the medicines you take, including prescription medicines (especially antibiotics and birth control pills) and over-the-counter medicines (especially acetaminophen), vitamins, herbal supplements or other medicines to treat diabetes, including sulfonylureas or insulin.

**How should I use Adlyxin?**

- Do not change your dose unless your healthcare provider has told you to change your dose.
- Check the label on the pen each time you give your Adlyxin injection to make sure you are using the correct medication.
- **You must activate each Adlyxin pen before you use it for the first time.**
- **Do not re-use or share your needles with other people. You may give other people a serious infection, or get a serious infection from them.**
- Inject your dose of Adlyxin under the skin (subcutaneously) of your abdomen, thigh, or upper arm. **Do not inject into a vein.**
- Change (rotate) your injection sites within the area you chose with each dose. Do not use the same spot for each injection.

**What are the possible side effects of Adlyxin?**

Adlyxin may cause serious side effects including:

- **severe allergic reactions.** Severe allergic reactions can happen with Adlyxin. Stop taking Adlyxin and get medical help right away if you have any symptoms of a severe allergic reaction.
- **low blood sugar (hypoglycemia).** Your risk for getting low blood sugar is higher if you use Adlyxin with another medicine that can cause low blood sugar, such as a sulfonylurea or insulin. The dose of your sulfonylurea or insulin medicine may need to be lowered while you use Adlyxin. Signs and symptoms of low blood sugar may include headache, drowsiness, weakness, hunger, fast heartbeat, dizziness, confusion, irritability, sweating, and feeling jittery. **Talk with your healthcare provider about how to treat low blood sugar.**
- **kidney problems (kidney failure).** In people who have kidney problems, diarrhea, nausea, and vomiting may cause a loss of fluids (dehydration) which may cause kidney problems to get worse.

**The most common side effects of Adlyxin include:**

- nausea, vomiting, headache, diarrhea, and feeling dizzy.

**Please see the full Prescribing Information for Adlyxin at [www.Adlyxin.com](http://www.Adlyxin.com).**

Thank you for watching.

SAUS.ADL.17.03.1014