



Above is a photo of an Adlyxin® (lixisenatide) injection 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).

### 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.

**Please see additional Important Safety Information for Adlyxin (lixisenatide) injection on the following page.**

**Please click link for full Prescribing Information for Adlyxin (lixisenatide) injection**

<http://products.sanofi.us/Adlyxin/Adlyxin.pdf>.

## Important Safety Information for Adlyxin (lixisenatide) injection (continued)

### 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 click link for full Prescribing Information for Adlyxin (lixisenatide) injection <http://products.sanofi.us/Adlyxin/Adlyxin.pdf>.

SAUS.ADL.17.06.4042