

MEDICATION GUIDE
ADLYXIN (ad-LIX-in)
(lixisenatide)
injection, for subcutaneous use

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.

Before using ADLYXIN, tell your healthcare provider if you have had:

- pancreatitis
- a history of alcoholism
- stones in your gallbladder (cholelithiasis)

These medical problems may make you more likely to get pancreatitis.

Stop taking ADLYXIN and call your healthcare provider right away if you have pain in your stomach area (abdomen) that is severe, and will not go away. The pain may be felt going from your abdomen through to your back. The pain may happen with or without vomiting. These may be symptoms of pancreatitis.

What is ADLYXIN?

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.
- ADLYXIN is not a substitute for insulin and is not for use in 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.
- ADLYXIN has not been studied in people who have a stomach problem that causes slow emptying of the stomach (gastroparesis). ADLYXIN is not for people with slow emptying of the stomach.
- **It is not known if ADLYXIN is safe and effective in children.**

Who should not use ADLYXIN?

Do not use ADLYXIN if you:

- are allergic to lixisenatide or any of the other ingredients in ADLYXIN. See the end of this Medication Guide for a complete list of ingredients in ADLYXIN.

Symptoms of a severe allergic reaction with ADLYXIN may include:

- swelling of your face, lips, tongue, or throat
- fainting or feeling dizzy
- problems breathing or swallowing
- very rapid heartbeat
- severe rash or itching

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 plan to become pregnant. It is not known if ADLYXIN will harm your unborn baby. Tell your healthcare provider if you are pregnant or plan to become pregnant while using ADLYXIN.

- are breastfeeding or plan to breastfeed. It is not known if ADLYXIN passes into your breast milk. Talk with your healthcare provider about the best way to feed your baby while you use ADLYXIN.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins and herbal supplements.

Especially tell your healthcare provider if you take:

- antibiotics or the pain reliever acetaminophen. Take these medicines at least 1 hour before using ADLYXIN. If you must take these medicines, take them with a meal or a snack. You should not take these medicines at the same time that you take ADLYXIN.
- birth control pills that are taken by mouth (oral contraceptives). ADLYXIN may lower the amount of the medicine in your blood from your birth control pills and they may not work as well to prevent pregnancy. Take your birth control pill at least 1 hour before your injection of ADLYXIN or at least 11 hours after your ADLYXIN injection.
- other anti-diabetes medicines, especially sulfonylurea medicines or insulin.

Ask your healthcare provider if you are not sure if your medicine is listed above.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist each time you get a new medicine.

How should I use ADLYXIN?

- Read the detailed **Instructions for Use** that comes with your ADLYXIN for instruction on using the ADLYXIN pen and injecting ADLYXIN.
- ADLYXIN comes as a disposable prefilled pen.
- Use ADLYXIN exactly as your healthcare provider tells you to. Do not change your dose unless your healthcare provider has told you to change your dose.
- Your healthcare provider should teach you how to inject ADLYXIN before you use it for the first time. If you have questions or do not understand the instructions, talk to your healthcare provider.
- Use ADLYXIN 1 time each day within 60 minutes (1 hour) before the first meal of the day and at the same time each day.
- If you miss a dose of ADLYXIN, take it within 1 hour before your next meal.
- 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.
- **Check your blood sugar levels.** Ask your healthcare provider what your blood sugar should be and when you should check your blood sugar levels.

Your dose of ADLYXIN and other diabetes medicines may need to change because of:

- change in level of physical activity or exercise, weight gain or loss, increased stress, illness, change in diet, or because of other medicines you take.

What are the possible side effects of ADLYXIN?

ADLYXIN may cause serious side effects including:

- See "[What is the most important information I should know about ADLYXIN?](#)"

- **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. See "**Who should not use ADLYXIN?**"
- **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 include:
 - headache
 - drowsiness
 - weakness
 - hunger
 - fast heartbeat
 - dizziness
 - confusion
 - irritability
 - sweating
 - 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
- feeling dizzy

These are not all the possible side effects of ADLYXIN. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ADLYXIN?

- Store your new, unused ADLYXIN pen in the refrigerator at 36°F to 46°F (2°C to 8°C).
- After activation, store your ADLYXIN pen at room temperature no higher than 86°F (30°C).
- Do not freeze ADLYXIN pens and do not use ADLYXIN if it has been frozen.
- Protect the pen from light.
- Replace the pen cap after each use to protect the container window from light.
- After activation, use the ADLYXIN pen for up to 14 days. Throw away the used ADLYXIN pen after 14 days, even if there is some medicine left in the pen.
- Do not use ADLYXIN past the expiration date printed on the label of the carton and pen.
- Do not store the ADLYXIN pen with the needle attached. If the needle is left on, this might lead to contamination and cause air bubbles which might affect your dose of medicine.
- See the **Instructions for Use** about the right way to throw away the ADLYXIN pen.
- **Keep your ADLYXIN pen, pen needles, and all medicines out of the reach of children.**

General information about the safe and effective use of ADLYXIN.

Medicines are sometimes prescribed for purposes other than those listed in a Medication Guide. Do not use ADLYXIN for a condition for which it was not prescribed. Do not give ADLYXIN to other people, even if they have the same symptoms that you have. It may harm them.


You can ask your pharmacist or healthcare provider for information about ADLYXIN that is written for health professionals.

What are the ingredients in ADLYXIN?

Active ingredient: lixisenatide

Inactive ingredients: glycerol 85%, sodium acetate trihydrate, methionine, metacresol, hydrochloric acid, sodium hydroxide solution and water for injection.

Manufactured by: sanofi-aventis U.S. LLC, Bridgewater, NJ 08807. A SANOFI COMPANY.

For more information, go to [www. ADLYXIN.com](http://www.ADLYXIN.com) or call sanofi-aventis at 1-800-633-1610. 

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