

# Lixisenatide Injection

(lix" i sen' a tide)

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**Brand Name(s):** Adlyxin<sup>®</sup>, Soliqua<sup>®</sup> (as a combination product containing Insulin Glargine and Lixisenatide)

or pharmacist if you have any questions. You can also visit the Food and Drug Administration (FDA) website (<http://www.fda.gov/Drugs/DrugSafety/ucm085729.htm>) to obtain the Medication Guide.

## WHY is this medicine prescribed?

Lixisenatide injection is used along with diet and exercise to treat type 2 diabetes (condition in which the body does not use insulin normally and therefore cannot control the amount of sugar in the blood). Lixisenatide injection is not used to treat type 1 diabetes (condition in which the body does not produce insulin and therefore cannot control the amount of sugar in the blood). Lixisenatide is not used instead of insulin to treat people with diabetes who need insulin. Lixisenatide injection is in a class of medications called incretin mimetics. It works by stimulating the pancreas to secrete insulin when blood sugar levels are high. Insulin helps move sugar from the blood into other body tissues where it is used for energy. Lixisenatide injection also slows the emptying of the stomach and causes a decrease in appetite.

Over time, people who have diabetes and high blood sugar can develop serious or life-threatening complications, including heart disease, stroke, kidney problems, nerve damage, and eye problems. Using medication(s), making lifestyle changes (e.g., diet, exercise, quitting smoking), and regularly checking your blood sugar may help to manage your diabetes and improve your health. This therapy may also decrease your chances of having a heart attack, stroke, or other diabetes-related complications such as kidney failure, nerve damage (numb, cold legs or feet; decreased sexual ability in men and women), eye problems, including changes or loss of vision, or gum disease. Your doctor and other healthcare providers will talk to you about the best way to manage your diabetes.

Your doctor or pharmacist will give you the manufacturer's patient information sheet (Medication Guide) when you begin treatment with lixisenatide injection and each time you refill your prescription. Read the information carefully and ask your doctor

## HOW should this medicine be used?

Lixisenatide injection comes as a prefilled dosing pen to inject subcutaneously (under the skin). It is usually injected once a day, within one hour (60 minutes) before the first meal of the day. Use lixisenatide injection at around the same time every day. Follow the directions on your prescription label carefully, and ask your doctor or pharmacist to explain any part you do not understand. Use lixisenatide injection exactly as directed. Do not use more or less of it or use it more often than prescribed by your doctor.

Your doctor will probably start you on a low dose of lixisenatide and then increase your dose after 14 days.

Lixisenatide injection controls diabetes but does not cure it. Continue to use lixisenatide injection even if you feel well. Do not stop using lixisenatide injection without talking to your doctor.

You will need to buy needles separately. Ask your doctor or pharmacist what type of needles you will need to inject your medication. Be sure to read and understand the manufacturer's instructions for injecting lixisenatide. Also make sure you know how and when to set up a new pen. If you are blind or have poor eyesight do not use this pen without help. Ask your doctor or pharmacist to show you how to use the pen. Follow the directions carefully.

Always look at the lixisenatide solution before you inject it. It should be clear, colorless, and free of particles. Do not use lixisenatide if it is colored, cloudy, thickened, or contains solid particles, or if the expiration date on the pen has passed.

Lixisenatide injection can be administered in the thigh (upper leg), abdomen (stomach area), or upper arm. Use a different site for each injection. Allow the

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pen to warm to room temperature before using it if stored in the refrigerator.

Never reuse needles and never share needles or pens. Always remove the needle right after you inject your dose. Throw away needles in a puncture-resistant container. Ask your doctor or pharmacist how to dispose of the puncture resistant container.

**Are there OTHER USES for this medication?**

This medication may be prescribed for other uses; ask your doctor or pharmacist for more information.

**What SPECIAL PRECAUTIONS should I follow?**

Before taking lixisenatide injection,

- tell your doctor and pharmacist if you are allergic to lixisenatide, exenatide (Bydureon, Byetta), liraglutide (Saxenda, Victoza), any other medications, or any of the ingredients in lixisenatide injection. Ask your pharmacist or check the Medication Guide for a list of the ingredients.
- tell your doctor and pharmacist what prescription and nonprescription medications, vitamins, nutritional supplements, and herbal products you are taking or plan to take. It is especially important to tell your doctor about all the medications you take by mouth because lixisenatide may change the way your body absorbs these medications. If you are taking pain medications such as acetaminophen (Tylenol), or antibiotics, take them at least one hour before lixisenatide injection. If you are taking oral contraceptives (birth control pills) take them at least 1 hour before, or 11 hours after using lixisenatide injection. Also, be sure to mention any of the following medications: chlorpropamide (Diabinese), digoxin (Lanoxin), glimepiride (Amaryl, in Duetact), glipizide (Glucotrol), glyburide (DiaBeta, Glynase, in Glucovance), insulin, tolazamide, and tolbutamide. Your doctor may need to change the doses of your medications or monitor you carefully for side effects.
- tell your doctor if you drink or have ever drunk large amounts of alcohol, or if you have or have ever had severe stomach problems, including

gastroparesis (slowed movement of food from the stomach to the small intestine), or problems digesting food; pancreatitis (swelling of the pancreas); gallstones (solid deposits that form in the gallbladder); or kidney disease.

- tell your doctor if you are pregnant, plan to become pregnant, or are breastfeeding. If you become pregnant while taking lixisenatide injection, call your doctor.
- ask your doctor what to do if there is a large change in your diet, exercise, or weight; or if you get sick, develop an infection or fever, experience unusual stress, or are injured. These changes and conditions can affect your blood sugar and the amount of lixisenatide injection you may need.

**What SPECIAL DIETARY instructions should I follow?**

Be sure to follow all exercise and dietary recommendations made by your doctor or dietitian. It is important to eat a healthy diet.

**What should I do IF I FORGET to take a dose?**

Inject the missed dose within 1 hour (60 minutes) before your next meal. However, if it is almost time for the next dose, skip the missed dose and continue your regular dosing schedule. Do not inject a double dose to make up for a missed one.

**What SIDE EFFECTS can this medicine cause?**

This medication may cause changes in your blood sugar. You should know the symptoms of low and high blood sugar and what to do if you have these symptoms.

Lixisenatide injection may cause side effects. Tell your doctor if any of these symptoms are severe or do not go away:

- nausea
- vomiting
- diarrhea
- constipation

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- indigestion
- bloating
- headache
- pain, itching, or redness at the injection site

Some side effects can be serious. If you experience any of these symptoms, stop taking lixisenatide injection and call your doctor immediately or get emergency medical treatment:

- ongoing pain that begins in the upper left or middle of the stomach but may spread to the back, with or without vomiting
- hives
- rash
- itching
- pounding heartbeat
- fainting or feeling dizzy
- swelling of the eyes, face, mouth, tongue, throat, feet, ankles, or lower legs
- difficulty swallowing or breathing
- hoarseness
- decreased urination,
- very dry mouth or skin or extreme thirst

Lixisenatide injection may cause other side effects. Call your doctor if you have any unusual problems while taking this medication.

If you experience a serious side effect, you or your doctor may send a report to the Food and Drug Administration's (FDA) MedWatch Adverse Event Reporting program online (<http://www.fda.gov/Safety/MedWatch>) or by phone (1-800-332-1088).

**What should I know about STORAGE and DISPOSAL of this medication?**

Keep this medication in the container it came in, tightly closed, and out of reach of children. Store it away from light, heat, dust and dirt. Store unused lixisenatide pens in the refrigerator (36°F to 46°F [2°C to 8°C]). Once a lixisenatide pen is in use, store it at room temperature (below 86°F [30°C]) with its cap

on. Do not freeze. Do not use lixisenatide if it has been frozen. Dispose of lixisenatide pens in a puncture-resistant container after 14 days from its first use, even if there is some solution left in the pen.

When traveling, be sure to keep lixisenatide pens dry. Unused pens should be refrigerated or kept at a cold temperature between 36°F to 46°F (2°C to 8°C). Pens that are in use can be stored at room temperature up to 86°F [30°C] (not in a car glove compartment or other hot place).

Unneeded medications should be disposed of in special ways to ensure that pets, children, and other people cannot consume them. However, you should not flush this medication down the toilet. Instead, the best way to dispose of your medication is through a medicine take-back program. Talk to your pharmacist or contact your local garbage/recycling department to learn about take-back programs in your community. See the FDA's Safe Disposal of Medicines website (<http://goo.gl/c4Rm4p>) for more information if you do not have access to a take-back program.

**What should I do in case of OVERDOSE?**

In case of overdose, call your local poison control center at 1-800-222-1222. If the victim has collapsed or is not breathing, call local emergency services at 911.

Symptoms of overdose may include the following:

- nausea
- vomiting
- diarrhea
- abdominal pain or bloating
- indigestion
- constipation

**What OTHER INFORMATION should I know?**

Keep all appointments with your doctor and the laboratory. Your blood sugar and glycosylated hemoglobin (HbA1c) should be checked regularly to determine your response to lixisenatide injection. Your doctor will tell you how to check your response to this

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medication by measuring your blood or urine sugar levels at home. Follow these instructions carefully.

Do not let anyone else take your medication. Ask your pharmacist any questions you have about refilling your prescription.

It is important for you to keep a written list of all of the prescription and nonprescription (over-the-counter) medicines you are taking, as well as any products such as vitamins, minerals, or other dietary supplements. You should bring this list with you each time you visit a doctor or if you are admitted to a hospital. It is also important information to carry with you in case of emergencies.

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