Adlyxin™
lixisenatide injection 20 mcg

Adlyxin (lixisenatide) injection dosing schedule

Step 1: Initiation

Days 1-14: Patients administer 10 mcg subcutaneously once daily for the first 14 days

Step 2: Maintenance

From Day 15 on: Patients administer maintenance dose of 20 mcg subcutaneously once daily

Discard each pen after 14 days, even if there are still doses available.

Indications and Limitations of Use for Adlyxin (lixisenatide) injection

Adlyxin is a glucagon-like peptide-1 (GLP-1) receptor agonist indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.

Limitations of Use:

- Has not been studied in patients with chronic pancreatitis or a history of unexplained pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Not for treatment of type 1 diabetes or diabetic ketoacidosis.
- Has not been studied in combination with short acting insulin.
- Has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis.

Important Safety Information for Adlyxin (lixisenatide) injection

Contraindications

- Adlyxin is contraindicated in patients with known hypersensitivity to lixisenatide or to any component of Adlyxin. Hypersensitivity reactions including anaphylaxis have occurred with Adlyxin.

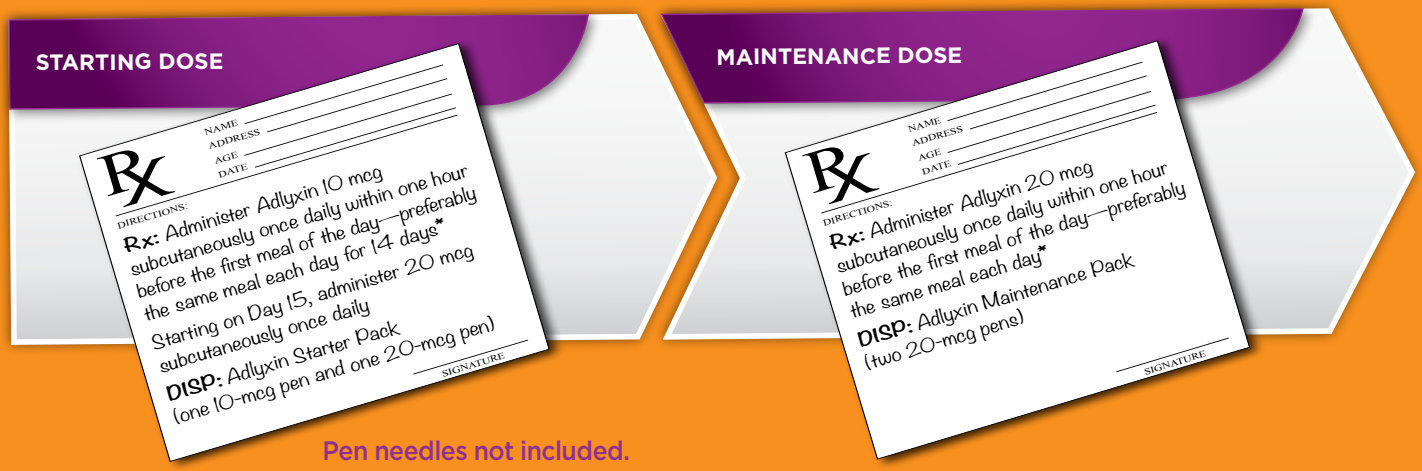
Warnings and Precautions

- **Anaphylaxis and Serious Hypersensitivity Reactions:** In clinical trials of Adlyxin there have been cases of anaphylaxis determined to be related to Adlyxin. Other serious hypersensitivity reactions including angioedema also occurred. If a hypersensitivity reaction occurs, patients must stop taking Adlyxin and promptly seek medical attention. Inform and closely monitor patients with a history of anaphylaxis or angioedema with another GLP-1 receptor agonist for allergic reactions, because it is unknown whether such patients will be predisposed to anaphylaxis.
- **Pancreatitis:** Acute pancreatitis, including fatal and non-fatal hemorrhagic or necrotizing pancreatitis, has been observed in patients treated with GLP-1 receptor agonists based on spontaneous postmarketing reports. In clinical trials of Adlyxin, there were cases of pancreatitis among some Adlyxin treated patients. After initiation of Adlyxin, observe patients carefully for signs and symptoms of pancreatitis (including persistent severe abdominal pain, sometimes radiating to the back and which may or may not be accompanied by vomiting). If pancreatitis is suspected, Adlyxin should promptly be discontinued and appropriate management should be initiated. If pancreatitis is confirmed, do not restart Adlyxin.
- **Never Share an Adlyxin Pen Between Patients, even if the needle is changed:** Pen sharing poses a risk for transmission of blood-borne pathogens.
- **Hypoglycemia with Concomitant Use of Sulfonylurea or Basal Insulin:** Patients receiving Adlyxin in combination with basal insulin or a sulfonylurea have an increased risk of hypoglycemia. Reduction of the dose of the sulfonylurea or basal insulin may be necessary.

Please see additional Important Safety Information for Adlyxin on next page.
Please click here for full Prescribing Information for Adlyxin.

Adlyxin™
lixisenatide injection 20 mcg

How to prescribe a 1-month (28 days) supply of Adlyxin™



Pen needles not included.

Patients may use pen needles approved for use with Adlyxin from Becton Dickinson, Ypsomed and Owen Mumford 8 mm long or shorter. If a dose is missed, administer Adlyxin within one hour prior to the next meal.

Important Safety Information for Adlyxin (lixisenatide) injection (cont'd)

Warnings and Precautions (cont'd)

- **Acute Kidney Failure:** There have been postmarketing reports of acute kidney injury and worsening of chronic renal failure, which may sometimes require hemodialysis in patients treated with GLP-1 receptor agonists. A majority of the reported events occurred in patients who had experienced nausea, vomiting, diarrhea, or dehydration. Monitor renal function when initiating or escalating doses of Adlyxin in patients with renal impairment reporting severe gastrointestinal reactions. Adlyxin is not recommended in patients with end stage renal disease.
- **Immunogenicity:** Patients may develop antibodies to lixisenatide following treatment with Adlyxin. A higher incidence of allergic reactions and injection site reactions occurred in antibody positive patients. If there is worsening glycemic control or failure to achieve targeted glycemic control, significant injection site reactions, or allergic reactions then alternative antidiabetic therapy should be considered.
- **Macrovascular Outcomes:** Clinical studies have not shown macrovascular risk reduction with Adlyxin or any other antidiabetic drug.

Most Common Adverse Reactions (≥5%)

The most common adverse reactions associated with Adlyxin include nausea, vomiting, headache, diarrhea, dizziness, and hypoglycemia.

Drug Interactions

Adlyxin delays gastric emptying, which may reduce the rate of absorption of orally administered medications. Use caution when coadministering oral medications that have a narrow therapeutic ratio or that require careful clinical monitoring. These medications should be adequately monitored when concomitantly administered with Adlyxin. If such medications are to be administered with food, patients should be advised to take them with a meal or snack when Adlyxin is not administered.

Oral medications dependent on threshold concentrations for efficacy, such as antibiotics, or medications for which a delay in effect is undesirable, such as acetaminophen, should be administered at least 1 hour before Adlyxin injection.

Patients taking oral contraceptives should be advised to take them at least 1 hour before Adlyxin administration or at least 11 hours after the dose of Adlyxin.

Use in Specific Populations

- **Pregnancy and Nursing Women:** The limited available data with lixisenatide in pregnant women are not sufficient to inform a drug-associated risk of major birth defects and miscarriage. Adlyxin should not be used during pregnancy unless the potential benefit justifies the potential risk to the fetus. There is no information regarding the presence of Adlyxin in human milk, the effects on the breastfed infant, or the effects on milk production.
- **Pediatric Use:** Safety and effectiveness of Adlyxin have not been established in pediatric patients below 18 years of age.

Please click here for full Prescribing Information for Adlyxin.

SANOFI

SAUS.ADL.17.03.0950