Adlyxin

(lixisenatide)

New Product Slideshow

MPR

Introduction

- **Brand name:** Adlyxin
- **Generic name:** Lixisenatide
- **Pharmacological class:** Glucagon-like peptide-1 (GLP-1) receptor agonist
- **Strength and Formulation:** 50mcg/mL, 100mcg/mL; soln for SC inj; contains m-cresol
- **Manufacturer:** Sanofi Aventis
- **How supplied:** Starter pack—2 prefilled pens (10mcg + 20mcg); Maintenance pack—2 prefilled pens (20mcg)
- **Legal Classification:** Rx

Adlyxin


20
mcg
PER DOSE
Adlyxin™
(lixisenatide) injection
For Single Patient Use Only
100 mcg per mL – 3 mL
For subcutaneous use only
Each dose contains 20 mcg (0.2 mL)

Indications

- As adjunct to diet and exercise, to improve glycemic control in **type 2 diabetes**

Limitations of Use

- **Not** studied in patients with history of unexplained pancreatitis; consider other antidiabetics
- **Not** a substitute for insulin
- **Not** for treating type 1 diabetes or ketoacidosis
- **Not** recommended with concurrent short-acting insulin
- **Not** recommended in gastroparesis

Dosage & Administration

- Give by SC inj once daily within the hour prior to first meal into abdomen, thigh, or upper arm; rotate inj sites

- **≥18yrs:** Initially 10mcg once daily for 14 days, then 20mcg once daily

Considerations for Special Populations

- **Pregnancy:** Use only if potential benefit justifies potential risk to the fetus
- **Nursing mothers:** Consider the need and adverse effects on the infant
- **Pediatric:** <18 years: not established
- **Elderly:** No overall differences observed in safety or efficacy
- **Renal impairment:** ESRD: not recommended

Warnings/Precautions

- **Do not** reuse or share pens, needles, or syringes between patients
- **Discontinue** if hypersensitivity reaction occurs
- **Monitor** for signs/symptoms of pancreatitis; discontinue if suspected; do not restart if confirmed
- History of **pancreatitis**: consider alternative antidiabetics
- **Renal impairment or severe GI reactions:** monitor when initiating or escalating doses

Interactions

- Increased risk of **hypoglycemia** with concomitant sulfonylureas or basal insulin (reduction in their doses may be needed)
- May affect **absorption** of oral drugs (delayed gastric emptying)
- **Caution** when concomitant oral drugs with narrow therapeutic ratio or that require careful monitoring
- Concomitant antibiotics, APAP, other drugs dependent on threshold concentration: administer ≥1hr before Adlyxin; for oral contraceptives, take ≥1hr before or 11hrs after Adlyxin

Adverse Reactions

- Nausea
- Vomiting
- Headache
- Diarrhea
- Dizziness
- Hypoglycemia
- Inj site reactions
- Allergic reactions
- Pancreatitis
- Renal failure
- Possible antibody formation

Mechanism of Action

- Lixisenatide is a GLP-1 receptor agonist that works by increasing glucose-dependent insulin release, decreasing glucagon secretion, and slowing gastric emptying

Clinical Trials

- Adlyxin has been studied as monotherapy, in combination with oral antidiabetics, and in combination with basal insulin ± oral antidiabetics
- Its efficacy was compared with placebo, exenatide, and insulin glulisine

Clinical Trials

- A 12-week, double-blind study (n=241) randomized patients with type 2 diabetes inadequately controlled on diet and exercise to either Adlyxin 20mcg once daily or placebo
- Treatment with Adlyxin led to **statistically significant reductions in HbA1c** from baseline at Week 12 (difference from placebo −0.65, [95% CI: −0.903,−0.399]; *P*<0.0001)

Clinical Trials

- A greater percentage of patients in the Adlyxin group achieved **HbA1c <7.0%** vs. the placebo group (44% vs. 24%)
- Patients in the Adlyxin group had a greater least-squares (LS) mean change from baseline in fasting plasma glucose (FPG) vs. placebo (−15.84mg/dL vs. +1.46mg/dL)
- The adjusted mean change in weight from baseline did not differ significantly between the groups

Clinical Trials

- A 24-week study (n=323) randomized patients with type 2 diabetes inadequately controlled on diet, exercise, and metformin to either Adlyxin 20mcg once daily or placebo

- Treatment with Adlyxin led to **statistically significant reductions in HbA1c** from baseline at Week 24 (difference from placebo −0.46, [95% CI:−0.640, −0.279]; *P*<0.0001)

Clinical Trials

- A greater percentage of patients in the Adlyxin group achieved HbA1c <7.0% vs. the placebo group (44% vs. 22%)
- Patients in the Adlyxin group had a greater LS mean change from baseline in FPG vs. placebo (−16.88mg/dL vs. −7.25mg/dL)
- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

http://www.empr.com/adlyxin/drug/34644/