

Soliqua 100/33

(insulin glargine, lixisenatide)



New Product
Slideshow

MPR

Introduction

- **Brand name:** Soliqua 100/33
- **Generic name:** Insulin glargine (rDNA origin), lixisenatide
- **Pharmacological class:** Human insulin analog + glucagon-like peptide-1 (GLP-1) receptor agonist
- **Strength and Formulation:** 100 Units/mL + 33mcg/mL; soln for SC inj; contains m-cresol
- **Manufacturer:** Sanofi aventis
- **How supplied:** SoloStar prefilled pen (3mL)—5
- **Legal Classification:** Rx

SOLIQUA



Indications

- As adjunct to diet and exercise, to improve glycemic control in adults with **type 2 diabetes mellitus** inadequately controlled on basal insulin (<60 Units daily) or lixisenatide

Limitations of Use

- Not studied in patients with history of unexplained pancreatitis; consider other antidiabetics
- Not for use with other lixisenatide- or GLP-1 receptor agonist-containing products
- Not for treating type 1 diabetes mellitus or diabetic ketoacidosis
- Not recommended in gastroparesis
- Not studied in combination with prandial insulin

Dosage & Administration

- **Discontinue** lixisenatide or basal insulin prior to initiation
- Give by SC inj once daily within the hour prior to first meal into thigh, upper arm or abdomen; rotate inj sites
- **≥18yrs:** individualize; monitor and adjust as needed
- **Inadequately controlled on <30 Units of basal insulin or on lixisenatide:** initially 15 Units once daily
- **Inadequately controlled on 30–60 Units of basal insulin:** initially 30 Units once daily

Dosage & Administration

- Titrate dose by 2–4 Units weekly until desired FPG achieved; max 60 Units
- **If <15 Units or >60 Units daily required:** use alternative antidiabetic products
- **Switching from basal insulin or lixisenatide:** see full labeling

Considerations for Special Populations

- **Pregnancy:** Use only if potential benefit justifies potential risk to the fetus
- **Nursing mothers:** Consider benefits and adverse effects
- **Pediatric:** <18 years: not established
- **Elderly:** Exercise caution
- **Renal impairment:** ESRD: not recommended

Contraindication

- During episodes of hypoglycemia

Warnings/Precautions

- Instruct patients on diet, exercise, blood testing, proper administration of insulin, and management of hypoglycemia
- **Do not** reuse or share pens, needles, or syringes between patients
- **Discontinue** if hypersensitivity reactions occur

Warnings/Precautions

- **Monitor** for signs/symptoms of pancreatitis; discontinue if suspected; do not restart if confirmed
- History of **pancreatitis**: consider alternative antidiabetics
- **Increased risk** of hypo- or hyperglycemia if changes in physical activity, meal patterns, renal or hepatic function, insulin regimen and if acute illness occurs: monitor glucose more frequently and may need to adjust dose

Warnings/Precautions

- Monitor **potassium** levels in patients at risk for hypokalemia (eg, concomitant K^+ -lowering or K^+ -sensitive drugs)
- **Renal impairment or severe GI reactions:** monitor and avoid fluid depletion
- Elderly

Interactions

- **Do not** mix or dilute with other insulins or solutions
- **Concomitant** thiazolidinediones (TZDs) may cause fluid retention and heart failure; consider dose reduction or discontinue TZDs
- **Potentiated** by antidiabetic agents, ACE inhibitors, ARBs, disopyramide, fibrates, fluoxetine, MAOIs, pentoxifylline, pramlintide, propoxyphene, salicylates, somatostatin analogs, sulfonamide antibiotics

Interactions

- **Antagonized by** atypical antipsychotics, corticosteroids, danazol, diuretics, estrogens, glucagon, isoniazid, niacin, oral contraceptives, phenothiazines, progestogens, protease inhibitors, somatropin, sympathomimetics, thyroid hormones
- **Variable effects** with β -blockers, clonidine, lithium salts, alcohol, pentamidine

Interactions

- **Concomitant** β -blockers, clonidine, guanethidine, reserpine may blunt hypoglycemia
- Concomitant antibiotics, APAP, other drugs dependent on threshold concentration: administer **≥ 1 hr before** Soliqua; for oral contraceptives, take **≥ 1 hr before or 11hrs after** Soliqua

Adverse Reactions

- Hypoglycemia
- Allergic reactions
- Injection site reactions
- Nausea
- Nasopharyngitis
- Diarrhea
- Upper respiratory tract infection
- Headache
- Lipodystrophy
- Weight gain
- Hypokalemia

Mechanism of Action

- **Insulin** and its analogs lower blood glucose by stimulating peripheral glucose uptake and by inhibiting hepatic glucose production
- **Lixisenatide** increases glucose-dependent insulin release, decreases glucagon secretion, and slows gastric emptying

Clinical Trials

- A randomized, active-controlled, open-label, 2-treatment arm, multicenter study (n=736) compared the safety and efficacy of Soliqua 100/33 vs. insulin glargine 100 Units/mL
- At **Week 30**, there was an HbA1c reduction from baseline of -1.1% for Soliqua and -0.6% for insulin glargine

Clinical Trials

- The mean difference in **HbA1c reduction** between Soliqua and insulin glargine was -0.5 [95% CI: $-0.6, -0.4$]

- For more clinical trial data, see full labeling

New Product Monograph

- For more information view the product monograph available at:

<http://www.empr.com/soliqua/drug/34632/>