Not actual patients

SOLIQUA 100/33

DOSING AND GRADUAL TITRATION GUIDE

SOLIQUA 100/33 is a combination of a long-acting human insulin analog with a glucagon-like peptide-1 (GLP-1) receptor agonist (RA) 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 a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
- Not recommended for use in combination with any other product containing a GLP-1 receptor agonist.
- Not for treatment of type 1 diabetes mellitus or diabetic ketoacidosis.
- Not recommended for use in patients with gastroparesis.
- Has not been studied in combination with prandial insulin.

Important Safety Information

Contraindications

- During episodes of hypoglycemia.
- In patients with known hypersensitivity to the active substance(s) or to any of the product components.

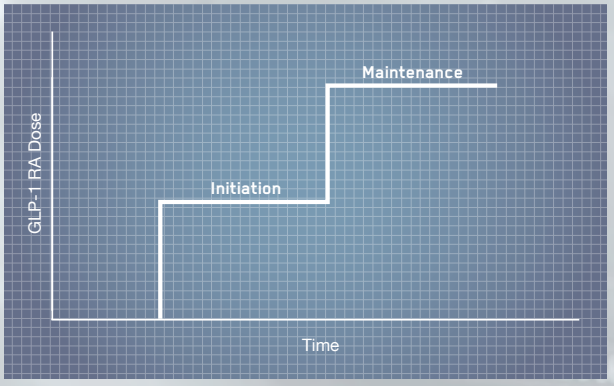
Please see full Important Safety Information on page 4.
Click here for full Prescribing Information.

SOLIQUA® 100/33
insulin glargine & lixisenatide injection
100 Units/mL & 33 mcg/mL

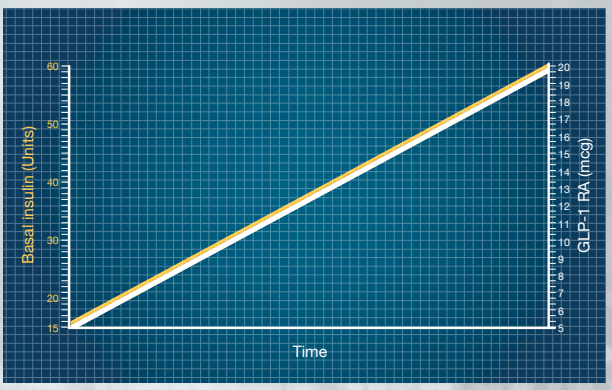
THE POWER TO GET TO GOAL

SOLIQUA 100/33 allows for gradual titration of the GLP-1 RA along with the basal insulin

Titration of stand-alone GLP-1 RA (lixisenatide)



Gradual titration of SOLIQUA 100/33

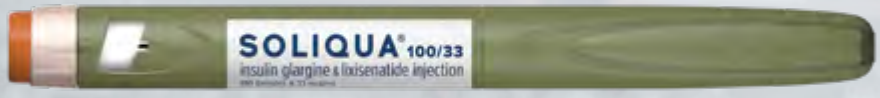


Important Safety Information

Warnings and Precautions

- **Anaphylaxis and Serious Hypersensitivity Reactions:** In clinical trials of lixisenatide, there have been cases of anaphylaxis and other serious hypersensitivity reactions including angioedema. Severe, life-threatening, generalized allergic reactions, including anaphylaxis and angioedema, can occur with insulins, including insulin glargine. If hypersensitivity reactions occur, discontinue SOLIQUA 100/33. Use caution in patients with a history of anaphylaxis or angioedema with another GLP-1 RA because it is unknown whether such patients will be predisposed to anaphylaxis.

SoloStar® technology you and your office staff will find familiar



TITRATE BY 2 – 4 UNITS WEEKLY UNTIL TARGET FPG IS REACHED

- SOLIQUA 100/33 is to be dosed based on the patient's metabolic needs, blood glucose monitoring results, and glycemic goals
- The dose on the SOLIQUA 100/33 SoloStar® pen can be adjusted in 1-unit increments

Storage information

- SOLIQUA 100/33 SoloStar pens should be stored in a refrigerator until opened; do not freeze
- Once opened, SOLIQUA 100/33 SoloStar pens should be stored at room temperature no higher than 77° F (25° C)
- Discard pen 28 days after first use
- Use only needles that are compatible for use with the SOLIQUA 100/33 prefilled pen

Package information

- Box (total volume): **3 mL x 5 pens =15 mL**
- Pen Cartridge (Volume): **3 mL = 300 Units**
- NDC: 0024-5761-05

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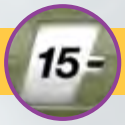
SOLIQUA® 100/33
insulin glargine & lixisenatide injection
100 Units/mL & 33 mcg/mL

THE POWER TO GET TO GOAL

The correct starting dose for appropriate patients not at target A1C

FOR PATIENTS UNCONTROLLED ON OADs



15 UNITS of SOLIQUA 100/33

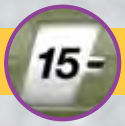
This starting dose provides 15 Units of Lantus® and 5 mcg of lixisenatide, a GLP-1 RA.

DOSING IS ONCE DAILY WITHIN THE HOUR PRIOR TO THE FIRST MEAL OF THE DAY

- The maximum dose of SOLIQUA 100/33 is 60 Units
- Use alternative treatment if doses below 15 units or above 60 units are required
- One Unit of SOLIQUA 100/33 contains 1 Unit of Lantus and 0.33 mcg of lixisenatide

FOR PATIENTS UNCONTROLLED ON THESE INJECTABLE THERAPIES

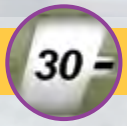
- GLP-1 RA
- Basal insulin <30 units



15 UNITS of SOLIQUA 100/33

This starting dose provides 15 Units of Lantus and 5 mcg of lixisenatide, a GLP-1 RA.

- Basal insulin ≥30 units



30 UNITS of SOLIQUA 100/33

This starting dose provides 30 Units of Lantus and 10 mcg of lixisenatide, a GLP-1 RA.

DOSING IS ONCE DAILY WITHIN THE HOUR PRIOR TO THE FIRST MEAL OF THE DAY

- The maximum dose of SOLIQUA 100/33 is 60 Units
- Use alternative treatment if doses below 15 units or above 60 units are required
- One Unit of SOLIQUA 100/33 contains 1 Unit of Lantus and 0.33 mcg of lixisenatide

Important Safety Information

Warnings and Precautions

- **Never Share a SOLIQUA 100/33 SoloStar® Pen between Patients:** Pen-sharing poses a risk for transmission of blood-borne pathogens, even if the needle is changed.

Please see full Important Safety Information on page 4.

Click here for full Prescribing Information.

SOLIQUA® 100/33
insulin glargine & lixisenatide injection
100 Units/mL & 33 mcg/mL

THE POWER TO GET TO GOAL

Important Safety Information

Contraindications

- During episodes of hypoglycemia.
- In patients with known hypersensitivity to the active substance(s) or to any of the product components.

Warnings and Precautions

- **Anaphylaxis and Serious Hypersensitivity Reactions:** In clinical trials of lixisenatide, there have been cases of anaphylaxis and other serious hypersensitivity reactions including angioedema. Severe, life-threatening, generalized allergic reactions, including anaphylaxis and angioedema, can occur with insulins, including insulin glargine. If hypersensitivity reactions occur, discontinue SOLIQUA 100/33. Use caution in patients with a history of anaphylaxis or angioedema with another GLP-1 RA 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 RAs. Cases of pancreatitis were reported in clinical trials of lixisenatide. After initiation of SOLIQUA 100/33, observe patients for signs and symptoms of pancreatitis (e.g., persistent severe abdominal pain, sometimes radiating to the back and which may be accompanied by vomiting). If pancreatitis is suspected, SOLIQUA 100/33 should promptly be discontinued. If pancreatitis is confirmed, restarting SOLIQUA 100/33 is not recommended and other antidiabetic therapies should be considered.
- **Never Share a SOLIQUA 100/33 SoloStar® Pen between Patients:** Pen-sharing poses a risk for transmission of blood-borne pathogens, even if the needle is changed.
- **Hyperglycemia or Hypoglycemia with Changes in Insulin Regimen:** Changes in insulin regimen including, strength, manufacturer, type, injection site or method of administration may affect glycemic control and predispose to hypoglycemia or hyperglycemia. Changes should be made cautiously and the frequency of blood glucose monitoring should be increased. Adjustments in concomitant oral antidiabetic treatment may be needed.

  Repeated insulin injections into areas of lipodystrophy or localized cutaneous amyloidosis may result in hyperglycemia; sudden change in the injection site (to unaffected area) has been reported to result in hypoglycemia. Advise patients to rotate injection site to unaffected areas and closely monitor for hypoglycemia.
- **Medication Errors:** SOLIQUA 100/33 contains two drugs. Do not administer more than 60 units of SOLIQUA 100/33, which may result in overdose of the lixisenatide component. Do not use other GLP-1 RAs. Accidental mix-ups between insulin products have been reported. Instruct patients to always check the label before administration. Do not withdraw SOLIQUA 100/33 from the pen with a syringe.
- **Hypoglycemia:** Hypoglycemia is the most common adverse reaction associated with insulin-containing therapy, which may be life-threatening. Increase frequency of glucose monitoring with changes to: insulin dosage, co-administered glucose lowering medications, meal pattern, physical activity, and in patients with renal or hepatic impairment and hypoglycemia unawareness.
- **Acute Kidney Injury:** There have been reports of acute renal failure and worsening of chronic failure, which may sometimes require hemodialysis in patients treated with GLP-1 RAs, such as lixisenatide. Some of these events were reported in patients without known underlying renal disease. Most reports occurred in patients who experienced nausea, vomiting, diarrhea, or dehydration; advise patients to take precautions to avoid fluid depletion. Monitor blood glucose and renal function in patients with renal impairment. SOLIQUA 100/33 is not recommended in patients with end-stage renal disease.
- **Immunogenicity:** Patients may develop antibodies to insulin and lixisenatide. If there is worsening glycemic control or failure to achieve targeted glycemic control, significant injection site reactions or allergic reactions, then other antidiabetic therapy should be considered.
- **Hypokalemia:** All insulin containing products can cause hypokalemia, which may be life-threatening. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia, and death. Monitor potassium levels in patients at risk of hypokalemia and treat if indicated.
- **Fluid Retention and Heart Failure with Concomitant Use of PPAR-gamma Agonists:** Fluid retention, which may lead to or exacerbate heart failure, can occur with concomitant use of thiazolidinediones (TZDs) and insulin. These patients should be observed for signs and symptoms of heart failure. If heart failure occurs, dosage reduction or discontinuation of TZD must be considered.
- **Macrovascular Outcomes:** Clinical studies have not shown macrovascular risk reduction with SOLIQUA 100/33.

Most Common Adverse Reactions

The most common adverse reactions reported in ≥5% of patients treated with SOLIQUA 100/33 include hypoglycemia, nausea, nasopharyngitis, diarrhea, upper respiratory tract infection, and headache.

Drug Interactions

- Certain drugs may affect glucose metabolism, requiring dose adjustment of SOLIQUA 100/33 and close monitoring of blood glucose.
- The signs of hypoglycemia may be reduced or absent in patients taking anti-adrenergic drugs (eg, beta-blockers, clonidine, guanethidine, and reserpine).
- The lixisenatide in SOLIQUA 100/33 delays gastric emptying, which may reduce the rate of absorption of orally administered medication with a narrow therapeutic ratio or that require careful clinical monitoring. If such medications are to be administered with food, do not co-administer with SOLIQUA 100/33.
- Antibiotics, acetaminophen, or other medications that are dependent on threshold concentrations for efficacy, or where a delay in effect is undesirable, should be administered at least 1 hour before SOLIQUA 100/33 injection.
- Oral contraceptives should be taken at least 1 hour before SOLIQUA 100/33 administration or 11 hours after.

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Click here for full Prescribing Information.

Don’t let cost and coverage be a barrier for you or your patients

ELIGIBLE COMMERCIALLY INSURED PATIENTS SAVE ON SOLIQUA 100/33

Pay as little as $9* for a 30-day supply

SOLIQUA 100/33 insulin glargine & lixisenatide injection
CO-PAY CARD

Terms and conditions apply

Click here for more information.

*This offer is for commercially insured patients and is not valid for prescriptions covered by or submitted for reimbursement under Medicare, Medicaid, VA, DOD, TRICARE, or similar federal or state programs including any state pharmaceutical programs. Void where prohibited by law. Savings card carries maximum savings of $365 per pack, up to 2 packs for each 30-day supply, for the duration of the program. Savings may vary depending on patient’s out-of-pocket costs. Upon registration, patient receives all program details. Sanofi US reserves the right to rescind, revoke, or amend the program without notice.

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