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

Dosing Calculator

Streamlined Treatment

Dosing Guide

Dosage Information

Titration Schedule

Coverage & Savings

Important Safety Infomation

References:

1. SOLIQUA 100/33 Prescribing Information.
2. Centers for Medicare & Medicaid Services.
3. Managed Markets Insight and Technology, LLC.

Dosing And Titration Guide

Indication:
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.

Insulin Glargine	Lixisenatide
60 units	20.0 mcg

*The dose window on the SOLIQUA 100/33 pen displays numbers for the even units and displays lines for the odd units.

Important Safety Information

Contraindications

- During episodes of hypoglycemia.
- In patients with known serious hypersensitivity to insulin glargine, lixisenatide, or to any of the product components.

Click here for full Prescribing Information.

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The SOLIQUA 100/33 SoloStar Pen Keeps Treatment Streamlined

Two Medicines, One SoloStar Pen: SOLIQUA 100/33 Includes Lantus® (insulin glargine injection) 100 Units/mL and Lixisenatide 33 mcg/mL[1]:

SOLIQUA 100/33 offers the power of two A1c-lowering medicines to help control blood sugar throughout the day:

- Insulin Glargine 100 units/mL (long-acting basal insulin)
- Lixisenatide 33mcg/mL (short-acting GLP-1 RA)

Once-daily treatment[1]

- Patients taking SOLIQUA 100/33 only need to inject once a day within the hour prior to the first meal of the day

Convenient cost and coverage[2,3]

- Single Co-pay for 2 medicines
- Broad commercial coverage
- Broad Medicare Part D coverage

Please see Important Safety Information below

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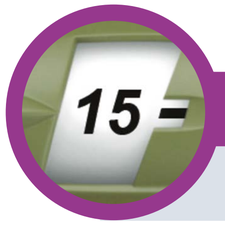
Dosing is Once Daily Within the Hour Prior to the First Meal of the Day[1]

The correct starting dose:

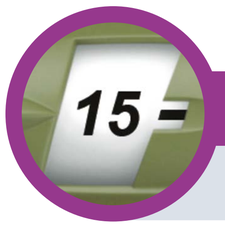
For Patients Uncontrolled on OADs and/or GLP-1 RA[1]



Units of SOLIQUA 100/33

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

For Patients Uncontrolled on Basal Insulin[1]



<30 units of basal insulin

Units of SOLIQUA 100/33

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

≥30 units of basal insulin

Units of SOLIQUA 100/33

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

FPG, fasting plasma glucose; GLP-1 RA, glucagon-like peptide-1 receptor agonist; OAD, oral antidiabetic drug.

References:

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Important Safety Information

Contraindications

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SOLIQUA 100/33 Dosage Information

- The maximum dose of SOLIQUA 100/33 is 60 Units/day
- 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

How SOLIQUA 100/33 Is Supplied

NDC#: 0024-5761-05

- 5 pens per box
- 3 mL SOLIQUA 100/33 single-patient-use pen
- 1 pen of SOLIQUA 100/33 includes 300 Units of insulin glargine and 99 mcg of lixisenatide

If SOLIQUA 100/33 dose is between 15 and 50 Units per day,

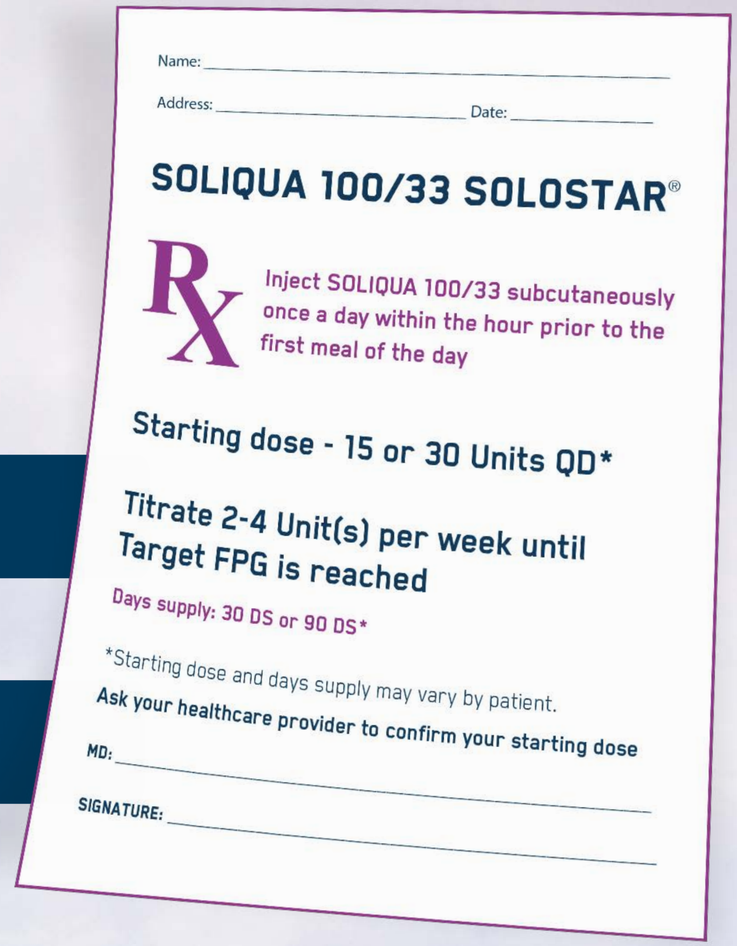
1 box is sufficient for a 30-day supply.

Or

If SOLIQUA 100/33 dose is between 51 and 60 Units per day,

2 boxes may be needed for a 30-day supply.

How to Write SOLIQUA 100/33[1]


Name: _____

Address: _____ Date: _____

SOLIQUA 100/33 SOLOSTAR®

Rx Inject SOLIQUA 100/33 subcutaneously once a day within the hour prior to the first meal of the day

Starting dose - 15 or 30 Units QD*

Titrate 2-4 Unit(s) per week until Target FPG is reached

Days supply: 30 DS or 90 DS*

*Starting dose and days supply may vary by patient.

Ask your healthcare provider to confirm your starting dose

MD: _____

SIGNATURE: _____

Important Safety Information

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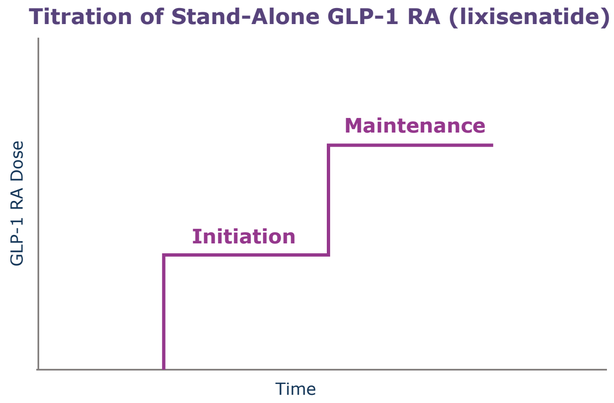
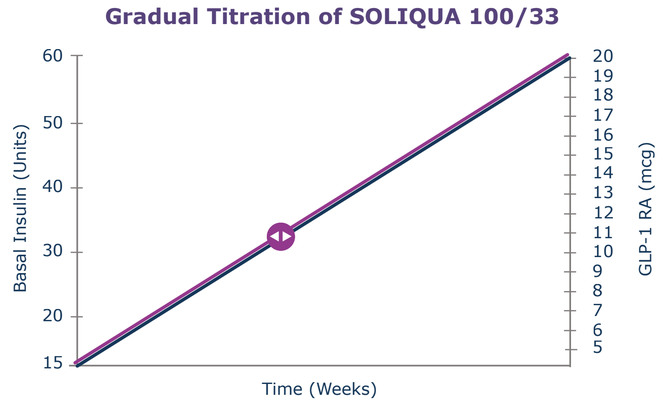
Titration Schedule: Titrate By 2 To 4 Units Weekly Until Target FPG is Reached[1]

- 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. Do not administer intravenously, intramuscularly, or via an insulin pump

-4	-2	No Change In Target FPG	+2	+4

Gradually Titrate GLP-1 RA and Basal Insulin With SOLIQUA 100/33[1]





30 U Basal Insulin | **10 mcg** GLP-1 RA

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Titration Schedule: Titrate By 2 To 4 Units Weekly Until Target FPG is Reached[1]

Eligible Medicare T2DM Patients May Pay A Max out-of-Pocket Cost of $35

The Inflation Reduction Act (IRA) caps the cost of insulin at $35 per month for seniors who have Medicare Part D. This ensures a predictable, stable Co-pay for SOLIQUA 100/33, and extends to all Part D plans that cover SOLIQUA 100/33.

Low Income Subsidy (Extra Help) eligible patients pay no more than $10.35 per month.

9 out of 10 Medicare Part D patients have access to SOLIQUA 100/33 for a max out of pocket of **$35** per month **ALL YEAR LONG**

9 out of 10 of Commercial Patients Covered
Eligible Co-pay Card patients pay as low as $35/month*

*SOLIQUA® Savings Program: This savings program is not insurance. This offer is not valid for prescriptions covered by or submitted for reimbursement, in whole or in part, under Medicare, Medicaid, VA, DOD, TRICARE, similar federal or state programs, including any state pharmaceutical programs. If you have an Affordable Care (Health Care Exchange) plan, you may still be qualified to receive and use this savings card. Please note: the Federal Employees Health Benefits (FEHB) Program is not a federal or state government health care program for purposes of the savings program. Void where prohibited by law.
For the duration of the program, eligible commercially insured patients who are payer approved may pay as little as $35 for a 30-day supply, with a maximum savings of $365 per pack, up to 2 packs, for each 30-day supply. Eligible commercially insured patients who are payer rejected and cash paying patients may pay as little as $99 per pack, up to 2 packs, for each 30-day supply. Savings may vary depending on patients' out-of-pocket costs. The SOLIQUA® Savings Program applies to the cost of medication. There are other relevant costs associated with overall treatment. Sanofi reserves the right to rescind, revoke, terminate, or amend this offer, eligibility, and terms of use at any time without notice. Upon registration, patients will receive all program details. For questions regarding your eligibility or benefits, or if you wish to discontinue your participation, call the SOLIQUA® Savings Program at (855) 262-5295 (8:00 am-8:00 pm EST, Monday-Friday).

Click Here for Formulary Look-Up and to See Which Plans Include SOLIQUA 100/33

Important Safety Information

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Indication

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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.

Contraindications

- During episodes of hypoglycemia.
- In patients with known serious hypersensitivity to insulin glargine, lixisenatide, 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. There have been reports of serious hypersensitivity reactions, including anaphylactic reactions and angioedema, in patients treated with SOLIQUA 100/33. 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 itis 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

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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 SOLIQUA 100/33. 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.
- **Acute Gallbladder Disease:** Acute events of gallbladder disease such as cholelithiasis or cholecystitis have been reported in GLP-1 receptor agonist trials and post-marketing. If cholelithiasis is suspected, gallbladder studies and appropriate clinical follow-up are indicated.

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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, 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.