



Soliqua[®] 100/33 (insulin glargine and lixisenatide) – Expanded indication

- On February 27, 2019, [Sanofi announced](#) the FDA approval of [Soliqua 100/33 \(insulin glargine and lixisenatide\)](#), as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus.
 - Previously, Soliqua was approved as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus inadequately controlled on basal insulin (less than 60 units daily) or [Adlyxin[™] \(lixisenatide\)](#).
 - Soliqua has not been studied in patients with a history of pancreatitis. Other antidiabetic therapies should be considered in patients with a history of pancreatitis.
 - Soliqua is not recommended for use in combination with any other product containing a glucagon-like peptide-1 (GLP-1) receptor agonist.
 - Soliqua is not indicated for use in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis.
 - Soliqua has not been studied in patients with gastroparesis and is not recommended in patients with gastroparesis.
 - Soliqua has not been studied in combination with prandial insulin.
- The approval of Soliqua's expanded indication was based on LixiLan-O, a 30-week, open-label study in 1,170 patients with type 2 diabetes uncontrolled with metformin and/or a second oral antidiabetic therapy. Patients were randomized to Soliqua, [Lantus[®] \(insulin glargine\)](#), or Adlyxin.
 - Soliqua provided a statistically significant improvement in HbA1c ($p < 0.0001$) vs. Lantus- or Adlyxin-treated patients (-1.6%, -1.3%, and -0.9%, respectively). The mean difference in HbA1c reduction between Soliqua and Lantus was -0.3% (95% CI: -0.4, -0.2) and -0.7% (95% CI: -0.8, -0.6) compared to Adlyxin.
 - In addition, more patients reached an HbA1c < 7% with Soliqua (74%) vs. Lantus (59%) or Adlyxin (33%).
- In patients naïve to basal insulin or to a GLP-1 receptor agonist, currently on less than 30 units of basal insulin, or on a GLP-1 receptor agonist, the recommended starting dosage of Soliqua is 15 units subcutaneously (SC) once daily.
- In patients inadequately controlled on 30 to 60 units of basal insulin, the starting dosage of Soliqua is 30 units SC once daily.
 - Soliqua should be injected within the hour prior to the first meal of the day.
 - The maximum daily dosage of Soliqua is 60 units (60 units of insulin glargine/20 mcg of lixisenatide).
 - Soliqua delivers doses from 15 to 60 units with each injection.
 - Refer to the Soliqua drug label for specific titration instructions.



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