Soliqua™ 100/33 (insulin glargine/lixisenatide) – New Drug Approval

- On November 21, 2016, Sanofi announced the FDA approval of Soliqua 100/33 (insulin glargine/lixisenatide) indicated as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus (T2DM) inadequately controlled on basal insulin (< 60 units daily) or lixisenatide.
    - Soliqua has not been studies in patients with a history of pancreatitis. Consider other antidiabetic therapies in patients with a history of pancreatitis.
    - Soliqua is not recommended for use in combination with any other product containing lixisenatide or another glucagon-like peptide 1 receptor agonist (GLP-1 RA).
    - Soliqua is not indicated for use in patients with type 1 diabetes mellitus (T1DM) 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.
- Soliqua is a once-daily, single injection fixed combination of a long-acting basal insulin analog, Lantus® (insulin glargine), and a GLP-1 RA, Adlyxin™ (lixisenatide).
- The efficacy and safety of Soliqua were demonstrated in a clinical study of 736 patients with T2DM randomized to Soliqua or insulin glargine. The primary efficacy endpoint was the reduction in baseline HbA1C to week 30.
    - The Soliqua group demonstrated a statistically significantly greater reduction in HbA1C vs. the insulin glargine group (-1.1% vs. -0.6%, respectively; $p < 0.01$).
    - The trial was designed to show the contribution of lixisenatide to glucose lowering and the results may not reflect real world clinical practice.
- Soliqua is contraindicated during episodes of hypoglycemia.
- Other warnings and precautions of Soliqua include anaphylaxis and serious hypersensitivity reactions, pancreatitis, hyperglycemia or hypoglycemia with changes in insulin regimen, overdose due to medication errors, acute kidney injury, immunogenicity, hypokalemia, fluid retention and heart failure with concomitant use of peroxisome proliferator-activated receptor-gamma agonists, and lack of macrovascular outcomes data. Soliqua should never be shared between patients, even if the needle is changed.
- The most common adverse reactions with Soliqua use were hypoglycemia, allergic reactions, nausea, nasopharyngitis, diarrhea, upper respiratory tract infection, and headache.
- Lixisenatide or basal insulin should be discontinued prior to initiation of Soliqua therapy.
- Soliqua is administered subcutaneously to the thigh, upper arm, or abdomen once daily.
- In patients inadequately controlled on < 30 units of basal insulin or on lixisenatide, the recommended Soliqua starting dose is 15 units (15 units of insulin glargine/5 mcg of lixisenatide) once daily.

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- In patients inadequately controlled on 30 to 60 units of basal insulin, the recommended Soliqua starting dose is 30 units (30 units of insulin glargine/10 mcg of lixisenatide) once daily.
    - Soliqua should be injected within the hour prior to the first meal of the day.
    - The maximum daily dosage is 60 units (60 units of insulin glargine/20 mcg of lixisenatide).
    - Soliqua delivers doses from 15 to 60 units with each injection.
    - Alternative antidiabetic products should be used if patients require a Soliqua daily dosage < 15 units or > 60 units.
    - Refer to the prescribing information for specific titration instructions.
- Sanofi plans to launch Soliqua 100/33 in January 2017. Soliqua will be available as a 3 mL single-patient-use pen containing 100 units of insulin glargine and 33 mcg of lixisenatide per mL.