SOLIQUA™
insulin glargine (100 U/mL) & lixisenatide

NAME AND PRESENTATION: Soliqua Solostar 100 units/ml + 50 microgram/ml solution for injection in a pre-filled pen. Each Pre-filled pen contains 300 units of insulin glargine and 150 micrograms lixisenatide in 3 ml solution. Each dose step contains 1 unit of insulin glargine and 0.5 micrograms lixisenatide. Soliqua 100 units/ml + 33 microgram/ml solution for injection in a pre-filled pen. Each pre-filled pen contains 300 units of insulin glargine and 100 micrograms of lixisenatide in 3 ml solution. Each dose step contains 1 unit of insulin glargine and 0.33 micrograms of lixisenatide. **THERAPEUTIC INDICATION:** Soliqua is indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise in addition to metformin with or without sodium-glucose co-transporter-2 (SGLT-2) inhibitors. **POSOLOGY AND METHOD OF ADMINISTRATION:** Soliqua is available in two pens, providing different dosing options, i.e. Soliqua (10-40) pen, Soliqua (30-60) pen respectively. The dose must be individualized based on clinical response and titrated according to the patient's need for insulin. For insulin naïve patients (on oral antidiabetic treatment or GLP-1 receptor agonist), the starting dose is 10 dose steps (10 units/5 mcg) should be administered via the Soliqua (10-40) pen. For patients on ≥ 20 to < 30units insulin glargine, the starting dose should be 20 dose steps (20 units/10 mcg) via the Soliqua (10-40) pen. For patients on ≥30 to ≤60 units of insulin glargine, the starting dose should be 30 dose steps (30 units/10mcg) via the Soliqua (30-60) pen. If a different twice-daily basal insulin or insulin glargine (300 units/ml) was used, the total daily dose used should be reduced by 20% to choose the Soliqua starting dose. For any other basal insulin the same rule as for insulin glargine (100 units/ml) should be applied. The maximum daily dose is 60 units insulin glargine and 20 mcg lixisenatide corresponding to 60 dose steps. Dosage titration: Recommended to optimize glycemic control via dose adjustment based on fasting plasma glucose. If patient starts with Soliqua (10-40) pen, the dose may be titrated up to 40 dose steps with pen. For doses >40 dose steps/day titration must be continued with Soliqua (30-60 pen) which allows titration up to 60 dose steps. Administration: Soliqua should be injected once a day within one hour prior to a meal. Soliqua is injected subcutaneously in the abdomen, deltoid or thigh. It is recommended to rotate the injection site with each injection. Each dose should be administered with a new needle. **CONTRAINDICATION**: Hypersensitivity to the active substances or to any of their excipients. **SPECIAL WARNINGS AND PRECAUTIONS OF USE**: Soliqua should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Use of Soliqua is not recommended in patients with severe gastrointestinal disease and severe renal impairments. Soliqua should be used with caution in patients receiving oral medicinal products that require rapid gastrointestinal absorption or with a history of acute pancreatitis. Hypoglycemia may occur if the dose of Soliqua is higher than required. Factors increasing the susceptibility to hypoglycemia require close monitoring and may necessitate dose-adjustments. Please refer to PI for more details. **INTERACTION:** Substances that may enhance the blood-glucose-lowering effect and increase susceptibility to hypoglycemia. **FERTILITY, PREGNANCY, AND LACTATION**: Soliqua should not be used during pregnancy. If a patient wishes to become pregnancy, or pregnancy occurs, treatment with Soliqua should be discontinued. While it is unknown whether insulin glargine or lixisenatide is excreted in human milk, Soliqua should not be used during breast-feeding. **EFFECTS OF ABILITY TO DRIVE AND USE MACHINES:** Soliqua has no or negligible influence on the ability to drive or use machines. The patient's ability to concentrate and react may be impaired as a result of hypoglycemia or hyperglycemia. **UNDESIRABLE EFFECTS:** Common adverse reactions are hypoglycemia, gastrointestinal (nausea, vomiting and diarrhea) and nervous system disorders (dizziness). Hypoglycemia and gastrointestinal adverse reactions may occur if a patient is dosed with more Soliqua than required. A small number of patients experienced injection site reactions (erythema, local edema and pruritus). For other adverse events please consult the approved product information. **SPECIAL PRECAUSTIONS FOR STORAGE: Not in-use pens:** Store in a refrigerator (2°C - 8°C). Do not freeze or place next to the freezer compartment or a freezer pack. Keep the pre-filled pen in the outer carton in order to protect from light. **In-use pens:** Store below 25°C. Do not refrigerate. Do not freeze. Do not store with attached needle. Store pen away from direct heat or direct light. The pen cap must be put back on the pen after each injection in order to protect from light. **SHELF-LIFE:** 24 months. Shelf-life after first use of the pen: 28 days. **PHARMACOTHERAPEUTIC GROUP:** Insulins and analogues for injection, long-acting. ATC code: A10AE54. **MARKETING AUTHORIZATION HOLDER:** Sanofi-Aventis group, 54, rue La Boétie - 75008 Paris, France. **MANUFACTURER:** Sanofi-Aventis Deutschland GmbH - 65926 Frankfurt am Main, Germany. Text revision: May 2023.

More detailed information available upon request from: Sanofi Winthrop Industrie, Mecca Street, Al Hijaz Towers for Investment, 8th Floor; PO BOX 922464, Amman 11192 – Jordan Tel: (962) 6 55 63 6 60.

To report an adverse event or if you have any medical enquiry, please call +964 751 740 2599 or email us at:
Levant.Pharmacovigilance@sanofi.com For Adverse Events; levant.medinfo@sanofi.com For Medical Enquiry; Quality.Levant@sanofi.com For Product Technical Complaints

MAT-IQ-2500047-1.0-03/2025