SOLIQUA™ Abbreviated Prescribing Information: KSA

1. NAME OF THE MEDICINAL PRODUCT: SOLIQUA™ 100 units/ml + 50 micrograms/ml solution for injection in a pre-filled pen and SOLIQUATM 100 units/ml + 33 micrograms/ml solution for injection in a pre-filled pen.
2. PRESENTATION AND QUALITATIVE/QUANTITATIVE COMPOSITION: SOLIQUA™ is available in two pens, providing different dosing options, i.e. SOLIQUATM (10-40) pen, SOLIQUA™ (30-60) pen respectively. The differentiation between the pen strengths is based on the dose range of the pen. SOLIQUA™ 100 units/ml + 50 micrograms/ml pre-filled pen delivers dose steps from 10-40 units of insulin glargine in combination with 5-20 mcg lixisenatide (SOLIQUATM (10-40) pen). SOLIQUA™ 100 units/ml + 33 micrograms/ml pre-filled pen delivers dose steps from 30-60 units of insulin glargine in combination with 10-20 mcg lixisenatide (SOLIQUA™ (30-60) pen).
3. 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 SGLT-2 inhibitors.
4. SPECIAL POPULATION: Elderly (≥65 years old): SOLIQUA™ can be used in elderly patients. The dose should be adjusted on an individual basis, based on glucose monitoring. Pediatric population: There is no relevant use of SOLIQUA™ in the pediatric population.
5. METHOD OF ADMINSTRATION: SOLIQUA™ is to be injected subcutaneously in the abdomen, deltoid, or thigh.
6. CONTRAINDICATIONS: Hypersensitivity to the active substances or to any of the excipients: Glycerol 85% 20 mg/ml , Methionine 3 mg/ml , Metacresol 2.7 mg/ ml , Zinc chloride 0.0626 mg/ml , Concentrated hydrochloric acid (for pH adjustment) q.s. pH 4.5, Sodium hydroxide (for pH adjustment) q.s. pH 4.5, Water for injections q.s. 1 ml.
7. SPECIAL WARNINGS AND PRECAUTIONS FOR USE: SOLIQUA™ should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Hypoglycaemia: Hypoglycaemia was the most frequently reported observed adverse reaction during treatment with SOLIQUA™. Acute pancreatitis: Use of glucagon-like peptide-1 (GLP-1) receptor agonists has been associated with a risk of developing acute pancreatitis. Severe gastrointestinal disease: Use of GLP-1 receptor agonists may be associated with gastrointestinal adverse reactions. SOLIQUA™ has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis and therefore, the use of SOLIQUATM is not recommended in these patients. Severe renal impairment: There is no therapeutic experience in patients with severe renal impairment (creatinine clearance less than 30 ml/min) or end-stage renal disease. Use is not recommended in patients with severe renal impairment or end-stage renal disease
8. PREGNANCY AND LACTATION: Women of childbearing potential: SOLIQUA™ is not recommended in women of childbearing potential not using contraception. Pregnancy: There is no clinical data on exposed pregnancies from controlled clinical studies with use of SOLIQUA™, insulin glargine, or lixisenatide. Lactation: SOLIQUA™ should not be used during breast-feeding.
OTHER SIDE EFFECTS: Common side effects are feeling dizzy, nausea, vomiting and diarrhea. .
MARKETING AUTHORISATION HOLDER sanofi-aventis groupe, 54, rue La Boétie 75008 Paris France, Abbreviated Prescribing Information based on SmPC last revised on December 2022. Always refer to full summary of product characteristics SmPC before prescribing.