Prescribing Information: Suliqua® ▼ (insulin glargine 100 units/ml and lixisenatide)

Please refer to the Summary of Product Characteristics (SmPC) before prescribing.

Presentations: ***Suliqua 100 units/ml + 50 microgram/ml solution for injection in a pre-filled pen***: Each containing 300 units of insulin glargine and 150µg lixisenatide in 3 ml solution. ***Suliqua 100 units/ml + 33 microgram/ml solution for injection in a pre-filled pen:*** Each containing 300 units of insulin glargine and 100µg lixisenatide in 3 ml solution.

Indication: Suliqua 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.

Dosage and administration: Suliqua is to be injected subcutaneously in the abdomen, deltoid, or thigh. The injection sites should be rotated within the same region from one injection to the next to reduce the risk of lipodystrophy and cutaneous amyloidosis. Patients should be instructed to always use a new needle. Suliqua must not be drawn from the cartridge of the pre-filled pen into a syringe to avoid dosing errors and potential overdose. Therapy with basal insulin or glucagon-like peptide-1 (GLP-1) receptor agonist or oral glucose lowering medicinal product other than metformin and SGLT-2 inhibitors should be discontinued prior to initiation of Suliqua. ***Suliqua 100 units/ml+50 µg/ml solution for injection in a pre-filled pen (10-40 pen):*** delivers dose steps from 10-40 units of insulin glargine in combination with 5-20µg lixisenatide. ***Suliqua 100 units/ml+ 33 µg/ml solution for injection in a pre-filled pen (30-60 pen):*** delivers dose steps from 30-60 units of insulin glargine in combination with 10-20µg lixisenatide. ***Starting dose:*** The starting dose of Suliqua is based on previous anti-diabetic treatment, and in order not to exceed the recommended lixisenatide starting dose of 10µg. ***Oral anti-diabetic treatment GLP-1 receptor agonist (insulin-naïve) patients:*** 10 dose steps (Suliqua 10-40 pen). ***Patients who have previously received ≥20<30 units insulin glargine (100 units/ml):*** 20 dose steps (Suliqua 10-40 pen). ***Patients who have previously received ≥30≤60 units insulin glargine (100 units/ml):*** 30 dose steps (Suliqua 30-60 pen). ***Patients who previously received twice daily basal insulin or insulin glargine (300 units/ml):*** total daily dose previously used should be reduced by 20% to choose the Suliqua starting dose. Suliqua is to be dosed in accordance with the individual patient's need for insulin. It is recommended to optimise glycaemic control via dose adjustment based on fasting plasma glucose. Close glucose monitoring is recommended during the transfer and in the following weeks. Max. daily dose 60 units insulin glargine and 20µg lixisenatide corresponding to 60 dose steps. Suliqua should be injected once a day within 1 hour prior to a meal. It is preferable that the prandial injection is performed before the same meal every day. Patients adjusting the amount or timing of dosing should only do so under medical supervision with appropriate glucose monitoring. ***Elderly (≥65 years old):*** Dose should be adjusted on an individual basis, based on glucose monitoring. No dose adjustment is required for lixisenatide. Data is limited in patients ≥75 years of age. ***Severe renal impairment (creatinine clearance less than 30 ml/min) and end-stage renal disease:*** Suliqua is not recommended. ***Mild to moderate renal impairment; Hepatic impairment:*** No dose adjustment is required for lixisenatide. Insulin requirements may be diminished due to reduced insulin metabolism. Frequent glucose monitoring and dose adjustment may be necessary. ***Paediatric population:*** No data available.

Contraindications: Hypersensitivity to the active substances or to any of the excipients.

Warnings and precautions: ***Traceability:*** In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded. Suliqua should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycaemic control following insulin injections at sites with these reactions. A sudden change in the injection site to an unaffected area has been reported to result in hypoglycaemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of antidiabetic medications may be considered. ***Hypoglycaemia:*** Hypoglycaemia was the most frequently reported observed adverse reaction during treatment with Suliqua. Hypoglycaemia may occur if the dose of Suliqua is higher than required. A number of factors may increase susceptibility to hypoglycaemia. These would require particularly close monitoring and may necessitate dose adjustment. ***Acute pancreatitis:*** Use of glucagon-like peptide-1 (GLP-1) receptor agonists has been associated with a risk of developing acute pancreatitis. There have been few reported events of acute pancreatitis with lixisenatide although a causal relationship has not been established. Patients should be informed of the characteristic symptoms of acute pancreatitis: persistent, severe abdominal pain. If pancreatitis is suspected, Suliqua should be discontinued; if acute pancreatitis is confirmed, lixisenatide should not be restarted. Caution should be exercised in patients with a history of pancreatitis. ***Severe gastrointestinal disease:*** Use of GLP-1 receptor agonists may be associated with gastrointestinal adverse reactions. Suliqua has not been studied in patients with severe gastrointestinal disease, including severe gastroparesis and therefore, the use of Suliqua is not recommended in these patients. ***Concomitant medicinal products:*** The delay of gastric emptying with lixisenatide may reduce the rate of absorption of orally administered medicinal products. Suliqua should be used with caution in patients receiving oral medicinal products that require rapid gastrointestinal absorption, require careful clinical monitoring or have a narrow therapeutic ratio. ***Dehydration:*** Patients treated with Suliqua should be advised of the potential risk of dehydration in relation to gastrointestinal adverse reactions and take precautions to avoid fluid depletion. ***Antibody formation:*** Administration of Suliqua may cause formation of antibodies against insulin glargine and/or lixisenatide. In rare cases, the presence of such antibodies may necessitate adjustment of the Suliqua dose in order to correct a tendency for hyperglycaemia or hypoglycaemia. ***Avoidance of medication errors:*** Patients must be instructed to always check the pen label before each injection to avoid accidental mix-ups between the two different strengths of Suliqua and mix-ups with other injectable diabetes medicinal products. ***Excipients:*** This medicinal product contains <1 mmol (23 mg) sodium per dose, thus is essentially 'sodium-free'. It also contains metacresol, which may cause allergic reactions. ***Interactions:*** Patients receiving medicinal products of either a narrow therapeutic ratio or medicinal products that require careful clinical monitoring should be followed closely, especially at the time of initiation of lixisenatide treatment. These medicinal products should be taken in a standardised way in relation to lixisenatide. If such medicinal products are to be administered with food, patients should be advised to, if possible, take them with a meal when lixisenatide is not administered. For oral medicinal products that are particularly dependent on threshold concentrations for efficacy, such as antibiotics, and gastro-resistant formulations containing substances sensitive to stomach degradation, patients should be advised to take those medicinal products at least 1 hour before or 4 hours after lixisenatide injection. ***Fertility, pregnancy and lactation:*** Suliqua is not recommended in women of childbearing potential not using contraception. No clinical data on exposed pregnancies from controlled clinical studies. Although >1000 pregnancy outcomes with insulin glargine indicate no specific adverse effects on pregnancy, there are no adequate data from the use of lixisenatide in pregnant women. Studies with lixisenatide in animals have shown reproductive toxicity. Suliqua should not be used during pregnancy. If a patient wishes to become pregnant, or pregnancy occurs, treatment with Suliqua should be discontinued. It is unknown whether insulin glargine or lixisenatide is excreted in human milk, thus should not be used during breastfeeding. Animal studies with lixisenatide or insulin glargine do not indicate direct harmful effects with respect to fertility.

Adverse reactions: ***Very common:*** Hypoglycaemia. ***Common***: Dizziness, Nausea, Diarrhoea, Vomiting, Injection Site Reactions. ***Not known:*** Cutaneous amyloidosis, lipodystrophy.

Legal classification: POM. **List price:** Suliqua 100 units/ml + 50µg/ml solution for injection in a pre-filled pen (10-40 pen) x3 pack: £67.50; Suliqua 100 units/ml + 33µg/ml solution for injection in a pre-filled pen (30-60 pen) x3 pack: £48.60. **Marketing authorisation holder:** Sanofi-aventis groupe, 54, rue La Boétie, 75008 Paris, France. **Marketing authorisation numbers:** EU/1/16/1157/001-006.

For more information please contact: Medical Information, Sanofi, 410 Thames Valley Park Drive, Reading, Berkshire, RG6 1PT, UK. uk-medicalinformation@sanofi.com. **Date of preparation:** September 2020.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to Sanofi Tel: 0800 090 2314. Alternatively, send via email to UK-drugsafety@sanofi.com