Abridged Prescribing Information

Fixed Ratio Combination of Insulin Glargine and Lixisenatide 100U + 50mcg /33mcg

Soliqua® SoloStar®

Composition: Soliqua® Solostar®100U + 50mcg /33mcg contains per mL 100 units insulin glargine and 50/33 mcg of lixisenatide

Indication: Soliqua® is indicated for the treatment of adults patients with Obesity with insufficiently controlled type 2 diabetes mellitus to improve glycemic control as an adjunct to diet and exercise in addition to metformin with or without SGLT2 inhibitors, when this has not been provided by metformin alone or metformin combined with another oral glucose lowering medicinal product (sulfonylurea, glinide, DPP-4 inhibitors or gliptins, and Sodium-glucose co- transporter 2 (SGLT2) inhibitors or gliflozins) or with basal insulin or with glucagon-like peptide-1 (GLP-1) receptor agonist

Dosage and administration: The starting daily dose of Soliqua® is 10 units (10 units of insulin glargine and 5 mcg of lixisenatide) and the maximum daily dose of Soliqua® is 60 units of Soliqua® (60 units insulin glargine and 20 mcg lixisenatide). Soliqua® should be administered subcutaneously once a day within 1 hour prior to any meal. It is preferable that the prandial injection of Soliqua® is performed before the same meal every day, when the most convenient meal has been chosen. If a dose of Soliqua® is missed, it should be injected within the hour prior to the next meal. The dose of Soliqua® must be individualized based on clinical response and is titrated based on the patient's need for insulin. The lixisenatide dose is increased or decreased along with insulin glargine dose and also depends on which pen is used. Soliqua® is titratable and available in two pens (10-40) pen or (30-60) pen, providing different dosing options.

Soliqua® is to be injected subcutaneously in the abdomen, deltoid, or thigh. The injection sites should be rotated within the same region (abdomen, deltoid, or thigh) from one injection to the next in order to reduce the risk of lipodystrophy and cutaneous amyloidosis. Patients should be instructed to always use a new needle.

Safety related information

Special populations: In pediatric patients below the age of 18 years, safety and effectiveness have not been established. Soliqua® can be used in elderly ≥ 65 years patient provided dose is adjusted on individual basis, based on glucose monitoring. In patient ≥ 75 years of age, therapeutic experience is limited. Frequent glucose monitoring and dose adjustment may be necessary for Soliqua® in patients with hepatic and renal impairment.

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

Warnings and precautions: Soliqua® should not be used in patients with type 1 diabetes mellitus or for the treatment of diabetic ketoacidosis. There have been few reported events of acute pancreatitis with lixisenatide, causal relationship not established. Inform patients of characteristic symptoms; persistent, severe abdominal pain. Discontinue Soliqua® if pancreatitis suspected; lixisenatide should not be restarted if acute pancreatitis confirmed. Caution in history of pancreatitis. Instruct patients to continuously rotate injection site to reduce risk of lipodystrophy and cutaneous amyloidosis; delayed insulin absorption and worsened glycemic control may occur after injection at affected sites. Sudden change in injection site to unaffected area has resulted in hypoglycemia; blood glucose monitoring is recommended after changing injection site and dose adjustment of antidiabetic medications may be considered. Hypoglycemia may occur if the dose of Soliqua® is higher than required, dose must be individualised based on clinical response and patient's need for insulin. Soliqua® not recommended in patients with severe gastrointestinal disease, including severe gastroparesis. Not recommended in severe renal impairment or end-stage renal disease. Caution in patients receiving oral medicinal products that require rapid gastrointestinal absorption, careful clinical monitoring or have a narrow therapeutic ratio. Advise patients to take precautions to avoid fluid depletion. In rare cases the presence of antibodies may necessitate adjustment of Soliqua® dose.

Interactions: No interaction studies with Soliqua® have been performed. For detailed information, please refer to the interaction section in the prescribing information.

Effects on ability to drive: Patients should be advised to take precautions to avoid hypoglycemia while driving and using machines.

Pregnancy and Lactation: Soliqua® should not be used during pregnancy or breast-feeding

Undesirable effects: The most frequently reported adverse reactions during treatment with Soliqua® were hypoglycemia and gastrointestinal adverse reactions. Very common: hypoglycemia. Common: dizziness, nausea, diarrhoea, vomiting.

For full prescribing information please contact: Sanofi Healthcare India Pvt. Ltd., Sanofi House, CTS No. 117-B, L&T Business Park, Saki Vihar Road, Powai, Mumbai – 400072

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