Prescribing Information: Toujeo® (insulin glargine 300 units/ml)

Presentation: Toujeo SoloStar pre-filled pens each ml contains 300 units of insulin glargine. SoloStar pen contains 1.5ml (450 units) of solution for injection. Indication: Treatment of diabetes mellitus in adults, adolescents, and children from the age of 6 years. **Dosage and Administration:** Toujeo is administered subcutaneously, by injection into the abdominal wall, the deltoid, or the thigh, once daily, at any time of the day, preferably at the same time every day. The dose regimen (dose and timing) should be adjusted according to individual response. Do not administer intravenously. In type 1 diabetes mellitus, Toujeo is to be used once daily with meal-time insulin and requires individual dose adjustments and must be combined with short-/rapid-acting insulin to cover mealtime insulin requirements. In patients with type 2 diabetes mellitus, the recommended daily starting dose is 0.2 units/kg followed by individual dose adjustments. Toujeo can also be given together with other anti-hyperglycaemic medicinal products. Switch between insulin glargine 100 units/ml and Toujeo: Insulin glargine 100 units/ml and Toujeo are not bioequivalent and are not directly interchangeable. When switching from insulin glargine 100 units/ml to Toujeo, this can be done on a unit-to-unit basis, but a higher Toujeo dose (approximately 10-18%) may be needed to achieve target ranges for plasma glucose levels. When switching from Toujeo to insulin glargine 100 units/ml, the dose should be reduced (approximately by 20%). Switching from other basal insulins to Toujeo: A change of dose and/or timing of the basal insulin and concomitant anti-hyperglycaemic treatment may be required. Switching from once-daily basal insulins to once-daily Toujeo can be done unit-to-unit based on the previous basal insulin dose. Switching from twice-daily basal insulins to once-daily Toujeo, the recommended initial Toujeo dose is 80% of the total daily dose of basal insulin that is being discontinued. Toujeo must not be mixed or diluted with any other insulin or other medicinal products. Close metabolic monitoring is recommended during a switch and in the initial weeks thereafter. Special Populations: Toujeo can be used in elderly people, renal and hepatic impaired patients, and children and adolescents from the age of 6 years. Paediatric: The safety and efficacy of Toujeo in children and adolescents below 6 years of age have not been established**.** **Contraindications:** Hypersensitivity to insulin glargine or any excipients. Precautions and Warnings: Toujeo is not the insulin of choice for the treatment of diabetic ketoacidosis. Hypoglycaemia: In case of insufficient glucose control or a tendency to hyper/hypoglycaemic episodes, the patient's adherence to the prescribed treatment regimen, injection sites, and proper injection technique, and all other relevant factors must be reviewed before dose adjustment is considered. Caution should be exercised, and intensified blood glucose monitoring is advisable for patients in whom hypoglycaemic episodes might be of clinical relevance and in those where dose adjustments may be required. The prolonged effect of subcutaneous insulin glargine may delay recovery from hypoglycaemia. Intercurrent illness: Requires intensified metabolic monitoring, and often it is necessary to adjust the insulin dose. Insulin antibodies: administration may cause insulin antibodies to form. Use with pioglitazone: Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for the development of cardiac failure. If the combination is used, patients should be observed for signs and symptoms of heart failure, weight gain, and oedema. Pioglitazone should be discontinued if any deterioration in cardiac symptoms occurs. Medication errors: Insulin labels must always be checked before each injection to avoid errors between Toujeo and other insulins. Patients must be instructed to never use a syringe to remove Toujeo from the SoloStar pre-filled pen. A new sterile needle must be attached before each injection. Needles must not be reused. **Pregnancy and lactation:** There are no data from exposed pregnancies in controlled clinical trials. However, there is a large amount of data on the use of insulin glargine 100 units/ml in pregnant women, indicating no specific adverse effects on pregnancy and no specific malformative or feto/neonatal toxicity. The use of Toujeo may be considered during pregnancy if clinically needed. It is unknown if insulin glargine is excreted in breast milk. Interactions: Substances that affect glucose metabolism may require adjustment of insulin glargine. **Adverse Reactions:** Very common: Hypoglycaemia. Common: Lipohypertrophy, injection site reactions, including redness, pain, itching, hives, swelling, or inflammation. Shelf life is 30 months. **Storage:** Before first use Store in a refrigerator (2°C-8°C). After first use, do not store the pen in a refrigerator. Only use your pen for up to 6 weeks after its first use below 30°C. Marketing Authorisation Holder: Sanofi-Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany. Text revision date: August 2020.

More detailed information available upon request from:

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To report an adverse event or if you have any medical enquiry, please call +962 6 55 63 6 60 or email us at:

Levant.medinfo@sanofi.com for medical enquiries. Quality.Levant@sanofi.com for product technical complaints.

Levant.Pharmacovigilance@sanofi.com for adverse events.