Prescribing Information

Toujeo® (insulin glargine 300 U/ml). Please refer to Summary of Product Characteristics prior to use of Toujeo. Toujeo Solostar pre-filled pens each contain 450 Units of insulin glargine in 1.5 ml of solution for injection, equivalent to 10.91 mg/ml.
Indications: Treatment of diabetes mellitus in adults**.**
Administration: Toujeo is administered subcutaneously once daily, at any time of the day, preferably at the same time every day. Do not administer intravenously. Insulin glargine dose regimen (dose and timing) should be individually adjusted. In type 1 diabetes mellitus, Toujeo must be combined with short-/rapid-acting insulin to cover mealtime insulin requirements. In patients with type 2 diabetes mellitus, Toujeo can also be given together with other anti-hyperglycaemic medicinal products. Close metabolic monitoring is recommended during the switch and in the initial weeks thereafter. Dose and timing of other antidiabetic medicines may need to be adjusted. Dose adjustments may also be required if the patient's weight or lifestyle changes, the timing of insulin dose is changed or other circumstances arise that increase susceptibility to hypo- or hyperglycaemia. Toujeo must not be mixed or diluted with any other insulin or other medicinal products. Mixing or diluting Toujeo changes its time/action profile and mixing causes precipitation. Insulin requirements may be diminished in the elderly or patients with renal or hepatic impairment. The safety and efficacy of Toujeo have not been established in children and adolescents below 18 years of age. No data are available.
Contraindications: Hypersensitivity to insulin glargine or any excipients.
Precautions and warnings: 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%) to reduce the risk of hypoglycaemia. Close metabolic monitoring is recommended during the switch and in the initial weeks thereafter. Toujeo is not the insulin of choice for treatment of diabetic ketoacidosis. 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. Insulin administration may cause insulin antibodies to form. Rarely, this may necessitate dose adjustment. Particular 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. Warning signs of hypoglycaemia may be changed, less pronounced or absent in certain risk groups, potentially resulting in severe hypoglycaemia and loss of consciousness. Risk groups include patients in whom glycaemic control is markedly improved, hypoglycaemia develops gradually, an autonomic neuropathy is present, or who are elderly. The prolonged effect of subcutaneous insulin glargine may delay recovery from hypoglycaemia. Cases of cardiac failure have been reported when pioglitazone was used in combination with insulin, especially in patients with risk factors for development of cardiac heart 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.

Pregnancy and lactation: No clinical data on exposed pregnancies from controlled clinical trials are available. A large amount of data on pregnant women (more than 1000 pregnancy outcomes with a medicinal product containing insulin glargine 100 units/ml (Lantus)) indicate no specific adverse effects on pregnancy and no specific malformative nor feto/neonatal toxicity of insulin glargine. Animal data do not indicate reproductive toxicity. The use of Toujeo may be considered during pregnancy, if clinically needed. Insulin requirements may decrease during the first trimester and generally increase during the second and third trimesters. Immediately after delivery, insulin requirements decline rapidly (increased risk of hypoglycaemia). Careful monitoring of glucose control is essential. It is unknown if insulin glargine is excreted in breast milk.
Adverse reactions: Very common: Hypoglycaemia. Prolonged or severe hypoglycaemia may be life-threatening. Common: Lipohypertrophy, injection site reactions, including redness, pain, itching, hives, swelling, or inflammation. Uncommon: Lipoatrophy. Rarely: Immediate-type allergic reactions; which may be associated with generalised skin reactions, angio-oedema, bronchospasm, hypotension and shock and may be life threatening; visual impairment, retinopathy and oedema. Very rare: Dysgeusia, myalgia. Insulin administration may cause insulin antibodies to form and may, in rare cases, necessitate adjustment of the insulin dose. Overdose may lead to severe and sometimes long-term and life-threatening hypoglycaemia. Please consult Summary of Product Characteristics for full details of the recognised side effects with Toujeo.
NHS price: £33.13 for pack of x3 1.5ml pens
Legal category: POM.
MA holder: Sanofi Aventis Deutschland GmbH, D-65926 Frankfurt am Main, Germany. **MA Numbers: SoloStar: 3 Pen pack: EU/1/00/133/034**
Full prescribing information is available from: Sanofi, One Onslow Street, Guildford, Surrey, GU1 4YS. Tel: 01483 505515 or the Sanofi Diabetes Care Line 08000 35 25 25.
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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to the Sanofi drug safety department on 01483 554242.