TOUJEO® (insulin glargine 300 units/ml) - Abbreviated Prescribing Information - KSA

NAME AND PRESENTATION: Toujeo 300 units/ml, solution for injection in a prefilled pen. 1 ml of solution contains 300 units of insulin glargine. Each SoloStar prefilled pen contains 1.5 ml of solution for injection (equivalent to 450 units). **THERAPEUTIC INDICATIONS:** Treatment of adults, adolescents and children, 6 years or older with diabetes mellitus. **POSOLOGY AND METHOD OF ADMINISTRATION:** Toujeo is a basal insulin for once-daily administration at any time of the day, preferably at the same time every day. When needed, patients can administer Toujeo up to 3 hours before or after their usual time of administration. The dose regimen (dose and timing) shouldbe adjusted according to individual response. In type 1 diabetes mellitus, Toujeo is to be used once daily 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. Toujeo can also be given together with other anti-hyperglycaemic medicinal products. **Switch:** When switching from insulin glargine 100 units/ml to Toujeo, this can be done on a unit-to-unit basis. When switching from a treatment regimen with an intermediate or long-acting insulin to a regimen with Toujeo, a change of the dose of the basal insulin may be required and the concomitant anti-hyperglycaemic treatment may need to be adjusted. Close metabolic monitoring is recommended during the switch and in the initial weeks thereafter. For switch details see full SmPC. **Special populations:** Toujeo can be used in elderly people, renal and hepatic impaired patients. Renal impairment & hepatic impairment: insulin requirements may be diminished. Elderly: progressive deterioration of renal function may lead to a steady decrease in insulin requirements. **Children:** the safety and efficacy of Toujeo in children and adolescents below 18 years of age have not been established. **Method of administration:** For subcutaneous use only. Toujeo must not be administered intravenously or in insulin infusion pumps. Toujeo SoloStar prefilled pen has been specifically designed for Toujeo, therefore no dose re-calculation is required. Toujeo must not be drawn from the cartridge of the SoloStar pre-filled pen into a syringe or severe overdose can result. For administration details see full SmPC. **CONTRA-INDICATIONS:** Hypersensitivity to the active substance or to any of the excipients listed in the full SmPC. **SPECIAL WARNINGS AND PRECAUTIONS FOR USE:** Toujeo is not the insulin of choice for the treatment of diabetic ketoacidosis. The prolonged effect of insulin glargine may delay recovery from hypoglycemia. If pioglitazone is used in combination with insulin, especially in patients with risk factors for development of cardiac heart failure, 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. For further details on special warnings and precautions for use see full SmPC. **DRUG INTERACTIONS:** Substances that may enhance or reduce the blood-glucose-lowering activity and increase susceptibility to hypoglycaemia are detailed in the full SmPC. **PREGNANCY AND LACTATION:** There is no clinical experience with use of Toujeo in pregnant women. For insulin glargine no clinical data on exposed pregnancies from controlled clinical studies are available. A large amount of data on pregnant women indicate no specific adverse effects on pregnancy and no specific malformative nor feto/neonatal toxicity of insulin glargine. The use of Toujeo may be considered during pregnancy if clinically needed. **EFFECTS ON ABILITY TO DRIVE:** Patient's ability to concentrate and react may be impaired as a result of hypoglycaemia or hyperglycaemia or, for example, as a result of visual impairment. Patients should be advised to take precautions to avoid hypoglycaemia whilst driving. **UNDESIRABLE EFFECTS:** Very common: Hypoglycemia. Hypoglycaemia may occur if the insulin dose is too high in relation to the insulin requirement. Common: Lipohypertrophy; injection site reactions. Lipodystrophy may occur at the injection site. Injection site reactions include redness, pain, itching, hives, swelling, or inflammation. For uncommon, rare & very rare adverse events consult the full SmPC. **OVERDOSAGE:** Mild episodes of hypoglycaemia can usually be treated with oral carbohydrates. More severe episodes may be treated with intramuscular/subcutaneous glucagon or concentrated intravenous glucose. **PHARMACOLOGICAL PROPERTIES:** ATC Code: A10A E04. **MARKETING AUTHORIZATION HOLDER:** Sanofi-Aventis Deutschland GmbH, D 65926 Frankfurt am Main, Germany. **LEGAL CATEGORY:** Medicinal product subject to medical prescription. For full prescribing information please refer to the full SmPC **dated January 2020.**