For the use only of a Registered Medical Practitioner or Hospital or a Laboratory

Abridged Prescribing Information

INSULIN GLARGINE INJECTION
TOUJEO® SoloStar®

COMPOSITION
Insulin glargine 300 U/ml. 1 ml contains 10.91 mg insulin glargine I.P., corresponding to 300 U of insulin glargine.
INDICATION
For the treatment of diabetes mellitus in adults.
DOSAGE AND ADMINISTRATION
Toujeo® is given subcutaneously. Toujeo® is administered once daily, at any time during the day, preferably at the same time every day. The recommended daily starting dose is 0.2 U/kg once daily followed by individual dosage adjustments. When needed, patients can administer their injections up to 3 hours before or after their usual time of administration. The desired blood glucose levels as well as the doses and timing of anti-hyperglycaemic medications must be determined and adjusted individually. Toujeo® is not the insulin of choice for the treatment of diabetic ketoacidosis. Changing from once-daily basal insulin products to once-daily Toujeo® can be done unit-to-unit based on the previous basal insulin dose. Changing from twice-daily basal insulin products to once-daily Toujeo®, the recommended initial Toujeo® dose is 80% of the total daily dose of the basal insulin that is being discontinued. Toujeo® must not be mixed with any other insulin products. Toujeo® must not be diluted. The safety and effectiveness of Toujeo® has not been established in paediatric patients (under 18 years of age). Toujeo® can be used in elderly patients, in patients with renal impairment and in patients with hepatic impairment. Close glucose monitoring is recommended.

SAFETY-RELATED INFORMATION
Contraindications:
Toujeo® must not be used in patients hypersensitive to insulin glargine or any of the excipients.
Warnings /Precautions:
General: Insulin treatment generally requires appropriate diabetes self-management skills including glucose monitoring, proper injection technique and hypo and hyperglycemia management. Patients and their relatives must know what steps to take if hyperglycemia or hypoglycemia occurs or is suspected, and they must know when to inform a physician. **Hypoglycemia**: The time of occurrence of hypoglycemia depends on the action profile of the insulins used and may, therefore, change when the treatment regimen is changed. As with all insulins, particular caution should be exercised, and intensified blood glucose monitoring is advisable, in patients in whom sequelae of hypoglycemic episodes might be of particular clinical relevance. The prolonged effect of subcutaneous Toujeo® may delay recovery from hypoglycemia. In patients with renal impairment or severe hepatic impairment, insulin requirements may be diminished. In the elderly, progressive deterioration of renal function may lead to a steady decrease in insulin requirements. Hypoglycemia can generally be corrected by immediate carbohydrate intake. So that initial corrective action can be taken immediately, patients must carry a minimum of 20 grams of carbohydrates with them at all times. **Intercurrent illness**: Requires intensified metabolic monitoring. In many cases urine tests for ketones are indicated, and often it is necessary to adjust the insulin dose. **Medication errors prevention**: Insulin label must always be checked before each injection to avoid medication errors between Toujeo® and other insulins. The patients must also be instructed to never use a syringe to remove Toujeo® from the SoloStar pre-filled pen into a syringe and not to re-use the needles. Patients must be instructed to perform continuous rotation of the injection site to reduce the risk of developing lipodystrophy and localized cutaneous amyloidosis. There is a potential risk of delayed insulin absorption and worsened glycemic 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 hypoglycemia. Blood glucose monitoring is recommended after the change in the injection site, and dose adjustment of antidiabetic medications may be considered
Pregnancy& Lactation:
It is essential for patients with pre-existing or gestational diabetes to maintain good metabolic control throughout pregnancy to prevent adverse outcomes associated with hyperglycaemia. Toujeo® can be used 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. Careful monitoring of glucose control is essential in such patients. Patients with diabetes must inform their doctor if they are pregnant or are contemplating pregnancy.
Adverse Reactions: Hypoglycemia is most frequent and may occur if the insulin dose is too high in relation to the insulin requirement. A marked change in glycaemic control may cause temporary visual impairment. Lipodystrophy may occur at the injection site. Localized cutaneous amyloidosis at the injection site has occurred with insulins. Hyperglycemia has been reported with repeated insulin injections into areas of localized cutaneous amyloidosis; hypoglycemia has been reported with a sudden change to an unaffected injection site. Allergic reactions at the

injection site includes redness, pain, itching, hives, swelling or inflammation. Immediate type allergic reactions are rare

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