Dosing and Titration for Toujeo® Max SoloStar®

The highest capacity basal insulin pen (900 Units) on the market - dialing up to 160 Units in a single injection.[1-6]

Toujeo® Max SoloStar®
insulin glargine injection 300 Units/mL

How to initiate and titrate to individualized goal[1]

The starting dose of Toujeo Max SoloStar is based on prior treatment

1 START/SWITCH

	Insulin-naive	Once-daily basal insulin	Twice-daily: NPH or insulin detemir
Type 1*	1/3 to 1/2 of the **total** daily insulin dose	**1:1** unit conversion to start†	80% of total daily dose
Type 2	0.2 Units/kg for Initial dose of Toujeo Max SoloStar		

*As a general rule, 0.2 to 0.4 units of insulin per kilogram of body weight can be used to calculate the initial total daily insulin dose in insulin naïve patients with type 1 diabetes. Mealtime insulin should be used to satisfy the remainder of the daily insulin requirements. For more dosing information please see the full PI.

†In clinical trials, patients started on, or changed to Toujeo required a higher dose than patients controlled on Lantus (insulin glargine injection) 100 units/mL.

2 DOSING

Weight based dosing for insulin naive adult T2DM patients

Weight in lb (pounds)	Starting insulin dose in Units[a]	Weight in lb (pounds)	Starting insulin dose in Units[a]
220-230	20	275-285	25
231-241	21	286-296	26
242-252	22	297-307	27
253-263	23	308-318	28
264-274	24	319-329	29

- [a]Units of Toujeo Max SoloStar are rounded down to the nearest even whole unit and are calculated based on a recommended starting dose of 0.2 Units/kg.
- Toujeo Max SoloStar delivers doses in 2 Unit increments.
- Toujeo Max SoloStar is recommended for patients requiring at least 20 units per day.
- When changing between Toujeo® SoloStar® and Toujeo Max SoloStar, if the patient's previous dose was an odd number, the dose should be increased or decreased by 1 unit.

3 TITRATE

- **Titrate Toujeo Max SoloStar no more frequently than every 3 to 4 days to help reduce the risk of hypoglycemia[1]**
- **Individualize and titrate the dosage of Toujeo Max SoloStar based on the individual's metabolic needs, blood glucose monitoring results, and glycemic control goal.**

Indication and Usage for Toujeo® U-300 (insulin glargine) injection

Toujeo is a long-acting human insulin analog indicated to improve glycemic control in adults and pediatric patients 6 years and older with diabetes mellitus.

Limitations of Use: Toujeo is not recommended for the treatment of diabetic ketoacidosis.

Important Safety Information for Toujeo U-300 (insulin glargine) injection

Contraindications

Toujeo is contraindicated during episodes of hypoglycemia and in patients hypersensitive to insulin glargine or any of the excipients in Toujeo.

Please see additional Important Safety Information for Toujeo on next page.

Please see accompanying full Prescribing Information.

Toujeo® Max SoloStar®
insulin glargine injection 300 Units/mL

Important Safety Information for Toujeo U-300 (insulin glargine) injection (cont'd)

Warnings and Precautions

Toujeo contains the same active ingredient, insulin glargine, as Lantus. The concentration of insulin glargine in Toujeo is 300 units per mL (U-300).

Insulin pens and needles must never be shared between patients. Do NOT reuse needles.

Monitor blood glucose in all patients treated with insulin. Modify insulin regimens only under medical supervision. Changes in insulin regimen, strength, manufacturer, type, injection site or method of administration may result in the need for a change in insulin dose or an adjustment in concomitant oral antidiabetic treatment. Changes in insulin regimen may result in hyperglycemia or hypoglycemia. Dosage adjustments are recommended to lower the risk of hypoglycemia when switching patients to Toujeo from another insulin therapy.

Repeated insulin injections into areas of lipodystrophy or localized cutaneous amyloidosis may result in hyperglycemia; sudden change in the injection site (to unaffected area) has been reported to result in hypoglycemia. Advise patients to rotate injection site to unaffected areas and closely monitor for hypoglycemia.

Unit for unit, patients started on, or switched to, Toujeo required a higher dose than patients controlled with Lantus. When switching from another basal insulin to Toujeo, patients experienced higher average fasting plasma glucose levels in the first few weeks of therapy until titrated to their individualized fasting plasma glucose targets. Higher doses were required in titrate-to-target studies to achieve glucose control similar to Lantus.

Hypoglycemia is the most common adverse reaction in patients treated with Toujeo and may be life-threatening. The long-acting effect of Toujeo may delay recovery from hypoglycemia compared to shorter-acting insulins.

Medication errors that may lead to hypoglycemia, such as accidental mix-ups between insulin products, have been reported. Patients should be instructed to always verify the insulin label before each injection.

Do not dilute or mix Toujeo with any other insulin or solution. If mixed or diluted, the solution may become cloudy, and the onset of action/time to peak effect may be altered in an unpredictable manner. Do not administer Toujeo via an insulin pump or intravenously because severe hypoglycemia can occur.

Severe, life-threatening, generalized allergy, including anaphylaxis, can occur. Discontinue Toujeo, monitor, and treat if indicated.

A reduction in the Toujeo dose may be required in patients with renal or hepatic impairment.

All insulins, including Toujeo, can lead to life-threatening hypokalemia. Untreated hypokalemia may cause respiratory paralysis, ventricular arrhythmia, and death. Closely monitor potassium levels in patients at risk of hypokalemia and treat if indicated.

Fluid retention, which may lead to or exacerbate heart failure, can occur with concomitant use of thiazolidinediones (TZDs) with insulin. These patients should be observed for signs and symptoms of heart failure. If heart failure occurs, dosage reduction or discontinuation of TZD must be considered.

Drug Interactions
Certain drugs may affect glucose metabolism, requiring insulin dosage adjustment and close monitoring of blood glucose. The signs of hypoglycemia may be reduced in patients taking anti-adrenergic drugs (e.g., beta-blockers, clonidine, guanethidine, and reserpine).

Adverse Reactions
Adverse reactions commonly associated with Toujeo include hypoglycemia, hypersensitivity reactions, injection site reactions, lipodystrophy, pruritus, rash, edema, and weight gain.

Important Safety Information for Toujeo U-300 (insulin glargine) injection SoloStar and Toujeo Max SoloStar

Toujeo SoloStar and Toujeo Max SoloStar are single-patient-use prefilled insulin pens. To help ensure an accurate dose each time, patients should follow all steps in the Instruction Leaflet accompanying their pen; otherwise, they may not get the correct amount of insulin, which may affect their blood glucose levels. It is especially important to perform a safety test when a patient is using a new pen for the first time.

Do not withdraw Toujeo from the SoloStar and Max SoloStar single-patient-use prefilled pens with a syringe.

Please see accompanying full Prescribing Information.

References: **1.** Toujeo Prescribing Information. **2.** Basaglar Prescribing Information. **3.** Lantus Prescribing Information. **4.** Levemir Prescribing Information. **5.** Tresiba Prescribing Information. **6.** Semglee Prescribing Information.

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