Indications and Usage for Toujeo®

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 treating diabetic ketoacidosis.

Important Safety Information

Contraindications

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

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

*Please see full prescribing information from the Toujeo.com website from where you printed this information.*

---

Weight based dosing for insulin naive adult T2DM patients

| Weight in lb (pounds) | Starting insulin dose in Units | Weight in lb (pounds) | Starting insulin dose in Units
|----------------------|-------------------------------|----------------------|-------------------------------
| 154-164              | 14                            | 242-252              | 22                            |
| 165-175              | 15                            | 253-264              | 23                            |
| 176-186              | 16                            | 264-274              | 24                            |
| 187-197              | 17                            | 275-285              | 25                            |
| 198-208              | 18                            | 286-296              | 26                            |
| 209-219              | 19                            | 297-307              | 27                            |
| 220-230              | 20                            | 308-318              | 28                            |
| 231-241              | 21                            | 319-329              | 29                            |

*Units of Toujeo® are rounded down to the nearest whole unit.

---

Adjust dose according to patient’s FPG goal

ADA recommends goals be individualized according to patient needs

Titrates Toujeo® no more frequently than every 3 to 4 days to minimize the risk of hypoglycemia

Individualize and titrate the dosage of Toujeo® based on the individual’s metabolic needs, blood glucose monitoring results, and glycemic control goal.

---

Indications and Usage for Toujeo® (insulin glargine injection) 300 Units/mL

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.
Important Safety Information (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.

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.

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 changed to, Toujeo required a higher dose than patients controlled with Lantus. When changing 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 of insulin therapy, including Toujeo, and may be life-threatening.

Medication errors, such as accidental mix-ups between basal insulin products and other insulins, particularly rapid-acting insulins, 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.

As with all insulins, Toujeo use 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 dose 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, allergic reactions, injection site reactions, lipodystrophy, pruritus, rash, edema and weight gain.

Important Safety Information for Toujeo® (insulin glargine injection) 300 Units/mL 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 the 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 full prescribing information from the Toujeo.com website from where you printed this information.

References

1. Toujeo Prescribing Information.