Toujeo®
insulin glargine 300U/mL

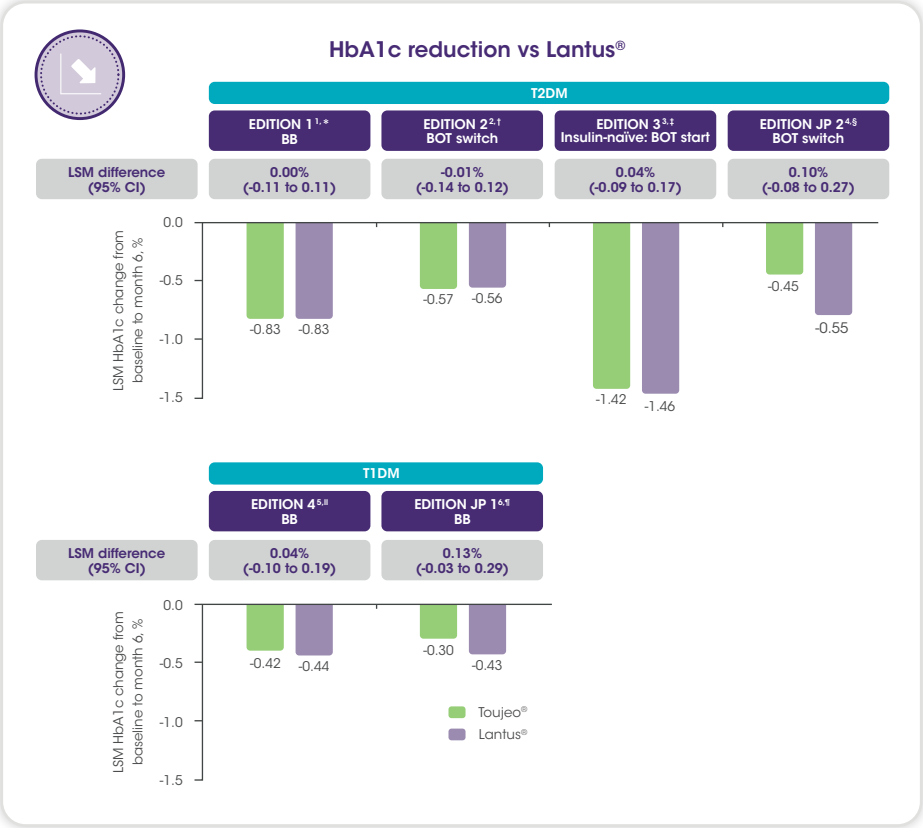
Upgrade Your Patients for Confidence in the Right Beat

Let your patients be carefree around the clock.

Together with assured glycaemic control.

That is Toujeo®.

Comparable HbA1c reduction vs Lantus®



* EDITION 1 was a 6-month, multinational, open-label, parallel group study. Adults with glycated hemoglobin A1c 7.0–10.0% (53–86 mmol/mol) were randomized to Toujeo® or Lantus® once daily with dose titration seeking fasting plasma glucose 4.4–5.6 mmol/L. Primary end point was HbA1c change from baseline; main secondary end point was percentage of participants with one or more confirmed (≤3.9 mmol/L) or severe nocturnal hypoglycaemia from week 9 to month 6.

† EDITION 2 was a multicenter, open-label, two-arm study. Adults receiving basal insulin plus OADs were randomized to Toujeo® or Lantus® once daily for 6 months. The primary end point was change in HbA1c. The main secondary end point was percentage of participants with one or more nocturnal confirmed (≤3.9 mmol/L) or severe hypoglycaemic events from week 9 to month 6.

‡ EDITION 3 study was a multicentre, open-label, parallel-group study. Participants were randomized to Toujeo® or Lantus® once daily for 6 months, discontinuing sulphonylureas and glinides, with a dose titration aimed at achieving pre-breakfast plasma glucose concentrations of 4.4–5.6 mmol/l. The primary endpoint was change in glycated haemoglobin from baseline to month 6. The main secondary endpoint was percentage of participants with ≥1 nocturnal confirmed (≤3.9 mmol/l) or severe hypoglycaemia from week 9 to month 6. Other measures of glycaemia and hypoglycaemia, weight change and insulin dose were assessed.

§ EDITION JP 2 study was a 6-month, multicentre, open-label, phase 3 study. Participants (n=241, male 61%, mean diabetes duration 14 years, mean weight 67 kg, mean body mass index 25 kg/m^2, mean glycated haemoglobin 8.02 %, mean basal insulin dose 0.24 U/kg/day) were randomized to Toujeo® or Lantus®, while continuing OAD(s). Basal insulin was titrated to target fasting self-monitored plasma glucose 4.4–5.6 mmol/l. The primary efficacy endpoint was HbA1c change over 6 months. Safety endpoints included hypoglycaemia and weight change.

‖ EDITION 4 study was a multicenter, randomized, four-arm, parallel-group, phase 3a study involving 549 participants with type 1 diabetes. Using a mealtime and basal insulin regimen, patients were randomized (1:1:1:1) open-label to Toujeo® or Lantus® and to morning or evening injection, continuing the mealtime analog, and followed up for 6 months. The primary efficacy end point was the overall change in HbA1c from baseline to month 6, regardless of injection time. Secondary end points included percentage to HbA1c <7.0% at month 6, change in pre-injection SMPG, within-participant variability of pre-injection SMPG, FPG 8-point SMPG profile, and daily insulin doses.

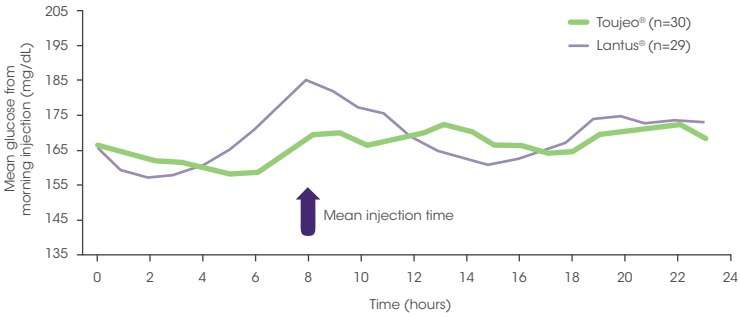
¶ The EDITION JP 1 study was a 6-month, multicentre, open-label, phase 3 study. Participants (n=243) were randomized to Toujeo® or Lantus® while continuing mealtime insulin. Basal insulin was titrated with the aim of achieving a fasting self-monitored plasma glucose target of 4.4–7.2 mmol/l. The primary endpoint was change in glycated haemoglobin over 6 months. Safety measures included hypoglycaemia and change in body weight.

BB=basal-bolus. BOT=basal-supported oral therapy.

More stable within-day glucose profile vs Lantus®7,**

CGM data

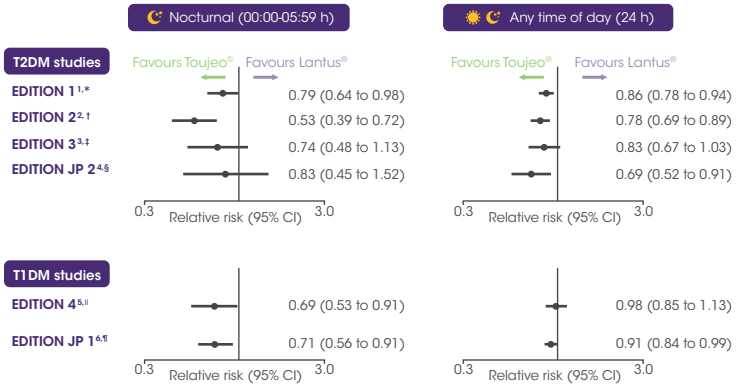
Activity profile at steady state in patients with Type 1 diabetes



The mean 24-hour glucose profiles obtained by CGM were smoother with Toujeo® than with Lantus® irrespective of injection time[7].

Lower risk of anytime and nocturnal hypoglycaemia vs Lantus®

Confirmed (≤3.9 mmol/L) or severe hypoglycaemia vs Lantus® from baseline to week 8



** The study was a 16-week, exploratory, open-label, parallel-group, two-period crossover study. 59 adults with type 1 diabetes were randomised (1:1:1:1) to once-daily Toujeo® or Lantus® given in the morning or evening (with crossover in the injection schedule). The primary efficacy end point was the mean percentage of time in the target glucose range (80–140 mg/dL), as measured using continuous glucose monitoring, during the last 2 weeks of each 8-week period. Additional end points included other CGM glycaemic control parameters, hypoglycaemia (per self-monitored plasma glucose), and adverse events.

Toujeo® insulin glargine 300U/mL

Upgrade your patients to Toujeo®[8]

Insulin-naïve patients

Start: 0.2 U/kg

Dose calculated based on weight

Weight range*		Dose range
50-75 kg	→	10-15 U/day

Patients on OD basal insulin

1:1 conversion

No dose recalculation required

Patients on BID basal insulin

80% of total previous daily insulin dose

* Weight change shown is illustrative only and dose calculation is not limited to this range.

BID=twice daily. OD=once daily.

References: 1. Riddle MC, et al. Diabetes Care. 2014;37:2755–2762. 2. Yki-Järvinen H, et al. Diabetes Care. 2014;37:3235–3243. 3. Bolli GB, et al. Diabetes Obes Metab. 2015;17:386–394. 4.Terauchi Y, et al. Diabetes Obes Metab. 2016;18:366–374. 5 Home PD, et al. Diabetes Care. 2015;38:2217–2225. 6. Matsuhisa M, et al. Diabetes Obes Metab. 2016;18:375–383. 7. Bergenstal RM, et al. Diabetes Care. 2017;40:554–560. 8. Toujeo® Hong Kong prescribing information. 2020 ver 1.

Abbreviated prescribing information: Presentation: Insulin glargine 300 IU/ml solution for injection. **Indications:** Treatment of diabetes mellitus in adults, adolescents and children from the age of 6 years. **Dosage:** Once daily (preferably at the same time every day up to 3 hours before or after the usual time of administration), with adjusted individual dosage. Please refer to the full prescribing information for guidelines on switching between other insulin preparations. **Administration:** Subcutaneous injection. Toujeo is NOT INTENDED FOR INTRAVENOUS USE since it could result in severe hypoglycaemia. Toujeo must not be drawn from the cartridge of the SoloStar pre-filled pen into a syringe or severe overdose can result. **Contraindications:** Hypersensitivity to insulin glargine or to any of the excipients. **Precautions:** Toujeo has not been studied in children below 6 years of age. **Elderly:** progressive deterioration of renal function may lead to a steady decrease in insulin requirements. **Renal impairment:** insulin requirements may be diminished due to reduced insulin metabolism. **Hepatic impairment:** insulin requirement may be diminished due to reduced capacity for gluconeogenesis and reduced insulin metabolism. Perform continuous rotation of injection site to reduce risk of lipodystrophy and cutaneous amyloidosis. Blood glucose monitoring is recommended after change in injection site. Hypoglycaemia. Intercurrent illness. Combination of Toujeo with pioglitazone. Medication errors prevention. **Interactions:** Effects enhanced by oral antidiabetics, ACEI, disopyramide, fibrates, fluoxetine, MAOIs, pentoxifylline, propoxyphene, salicylates, sulfonamide antibiotics. Effects reduced by corticosteroids, danazol, diazoxide, diuretics, glucagons, isoniazid, oestrogens and progestogens, phenothiazine derivatives, somatropin, sympathomimetics, or thyroid hormones, atypical antipsychotics and protease inhibitors. Beta-blockers, clonidine, lithium or alcohol may either potentiate or weaken the effects of insulin. Pentamidine may cause hypoglycaemia, followed by hyperglycaemia. The signs of adrenergic counter-regulation may be reduced or absent under the influence of sympatholytic medicinal products such as Beta-blockers, clonidine, guanethidine and reserpine. **Fertility, pregnancy and lactation:** Animal studies do not indicate direct harmful effects with respect to fertility and reproductive toxicity. The use of Toujeo may be considered during pregnancy if clinical needed. It is unknown whether insulin glargine is excreted in human milk. **Overdose:** Insulin overdose may lead to severe and sometimes long-term and life-threatening hypoglycaemia. Mild episodes of hypoglycaemia can usually be treated with oral carbohydrates. More severe episodes with coma, seizure or neurologic impairment may be treated with glucagon (intramuscular or subcutaneous) or concentrated glucose solution (intravenous). **Undesirable effects:** Hypoglycaemia, lipohypertrophy, injection site reactions. For common, uncommon, rare and very rare undesirable effects, please refer to the full prescribing information. **Storage:** Before first use: Store in a refrigerator (2°C - 8°C). Do not freeze. Protect from light. After first use: Store below 30°C. Use within 42 days. Do not freeze. **Preparation:** Toujeo 5 x 1.5ml (450IU) pre-filled pens. **Legal Classification:** Part 1 Poison **Full prescribing information is available upon request**.

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sanofi

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